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VINYL CHLORIDE: AN OCCUPATIONAL HEALTH HAZARD

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I. INTRODUCTION

Vinyl Chloride Monomer, a gas used to produce the second most widely used plastic in the United States, has been shown to be carcinogenic. Thousands of workers in the United States and other countries have been exposed to levels of this gas that now are presumed to be dangerous. The general public has also been exposed to low levels of vinyl chloride. The effects of these low levels are unknown. The Occupational Safety and Health Administration (OSHA) formulated an occupational standard for exposure to this gas which is presently being disputed in the U.S. Circuit Court. The major area of dispute seems to be whether OSHA's standard can be put into effect without forcing the vinyl chloride industries and vinyl-chloride-using plastic makers to cease operations. Some regulations protecting the general public from vinyl chloride in aerosol cans have been enacted and others, concerning environmental vinyl chloride and vinyl chloride residues in food, are being planned.

This report was prepared in response to inquiries from members of Congress concerning the various occupational and other health issues associated with vinyl chloride.

II. CHEMICAL PROPERTIES OF VINYL CHLORIDE (VCM)

Vinyl chloride monomer (VCM), Chemical Abstracts Service Registry No. 75014, has a molecular weight of 62.50 and a boiling point of -13.37°C. VCM is a colorless gas at room temperature and pressure with a pleasant sweetish smell that can be detected by humans in air at levels of 2000 parts per million (ppm). It is a synthetic organic chemical made from ethylene or acetylene and chlorine by any of several processes. VCM is explosive at levels between 1.2% and 52% by volume in air. Prolonged exposure to levels above 6000 ppm can produce symptoms of intoxication. Higher levels can produce unconsciousness. VCM is usually handled as a liquid under pressure. 1/ 2/

1/ American Industrial Hygiene Association. Hygiene Guide Series: Vinyl Chloride. Southfield, Michigan, American Industrial Hygiene Association, Aug., 1964: p.1-4.

2/ U.S. Occupational Safety and Health Administration. Final Environmental Impact Statement, Proposed Regulation: Vinyl Chloride. Washington, D.C., Sept. 5, 1974. p. 14-15.

III. AMOUNT OF INDUSTRIAL PRODUCTION AND USES OF POLYVINYL CHLORIDE (PVC)

Polyvinyl chloride (PVC) is now the number two plastic in the United States in :rms of tonnage production. Over 5.4 billion pounds (2.43 million metric tonnes) of nyl chloride and over 4.4 billion pounds (1.98 million metric tonnes) of polyvinyl ıloride are consumed annually. 3/

Synthesis of vinyl chloride is conducted in 15 plants in the United States. Poly- nyl chloride resin is produced in 37 plants in the United States. Five new PVC :sin plants are under construction and together with expansion of five others will .eld an additional annual capacity of 1.378 billion pounds. B.F. Goodrich, Co. is . largest U.S. producer of PVC resins. PVC resins are compounded with additives in)proximately 200 plants. About 7500 plants, employing 350,000 workers, are engaged ı fabricating products from PVC. 4/

The VCM-PVC industry for the past five years has shown an annually compounded rowth rate of 14%. PVC output has risen 70% in the past five years. Limits to r[illegible], until 1974, seemed to be based upon the availability of the petroleum feed- :ock necessary for the production of VCM. 5/

An Arthur D. Little study for the Society of Plastics Industries (SPI) states ıat about 2.2 million jobs in the U.S. depend on the PVC industry. The market value f the gas and the resin made from it is perhaps $1.5 billion. Wholesale values of all roducts made from PVC is about $3 billion. The Arthur D. Little study estimates that etween $65 and $90 billion dollars in sales and production would be lost annually if ıe material were banned. 6/

3/ Ibid. p. 42-43.

4/ Ibid.

5/ Putting VCM Emissions on Skids. Chemical Week, Sept. 18, 1974: p. 67.

6/ What's Ahead for Vinyl Makers: Slowdown or End of the Road? Chemical Week, July 3, 1974. p. 7-8.

97% of all VCM is used for the manufacture of homopolymer and copolymer resins. ıe remainder is utilized for the production of methyl chloroform, additives and pecial coatings and, until recently, aerosol propellants.

PVC is used in flooring and piping, apparel, insulation for electrical wiring, ackaging, upholstery, phonograph records, blood storage bags, medical devices, and n a multitude of other applications. The average General Motors car contains thirty o forty pounds of plastics manufactured from PVC. At 325 million pounds per year onsumption, packaging is a major outlet of PVC resin produced. 79 million pounds ere used for bottles in 1973. 1.34 billion pounds of PVC, 25% of total PVC consumption, ent to make pipe and fittings for building industry. 464 million pounds went into looring. Total construction markets for PVC were well over 2 billion pounds or close o 43% of consumption by all industries. Auto upholstery, seat covers, mats and deco- ative tops accounted for 256 million pounds. More than 400 million pounds are used nnually on wire and cable as insulation, or about 10% of total production. Film and [illegible] for packaging and coated fabrics account for 15% of all consumption. 7/

7/ Second Thoughts on Using PVC. Chemical Week, July 31, 1974. p. 19-20/

IV. INDUSTRIAL PRODUCTION METHODS

The vinyl chloride industry is composed of three segments: monomer producers, polymer producers and fabricators.

Vinyl chloride monomer is produced and shipped as a compressed liquid to polymerizations plants where the monomer is processed into homopolymer (consisting of only vinyl chloride) or copolymer (consisting of vinyl chloride and some other monomer) resins. The PVC copolymer or homopolymer is compounded with additives. Compounding may occur in the same plant that produces the basic resins, in the fabricating plant, or in a separate facility. Approximately 200 companies supply these compounded resins. Then, in granular form, as PVC paste (a fine powder with the texture of processed flour), or PVC latex (a stable suspension of PVC in liquid), at the fabrication point the compounded resin is reheated or otherwise treated to form final products, components of other equipment, or materials used various industries.

Production of the vinyl chloride monomer is a large-scale continuous process. There are relatively few employees in this segment of the industry because the processes lend themselves to automation. The Manufacturing Chemists Association (MCA) 8/ estimates that 1,500 people work in monomer production. Vinyl chloride monomer is synthesized from chlorine and petrochemical feedstocks (usually ethylene) in a continuous closed process. The plants are open to the air and resemble oil refineries. In some cases they are attached to them.

8/ U.S. Occupational Health and Safety Administration. Informal Hearing. Informal Fact-Finding Hearings on Vinyl Chloride. February 15, 1974. Unpublished.

The basic chemical reaction which forms the polyvinyl chloride from the vinyl chloride monomer can be stated simply as:

$$nCH_2 = CHCl \xrightarrow[\text{catalyst}]{\text{heat}} (CH_2\text{-}CHCl)_n$$

where n (or any particular number) of vinyl chloride molecules in the presence of heat and a catalyst join together to form a polymerized chain. 9/

Polymerization is a chain reaction. The polymer chains will average 2,000 monomer units with individual chains ranging from few to perhaps 10,000 units. The actual distribution of molecular weights of the polymer chains, upon which the properties of the plastic depends, is influenced by the polymerization method, the catalyst, the temperature, the fraction of monomer polymerized and the presence of impurities or additives which can terminate the growing chains. Comonomers such as vinyl acetate, vinylidene chloride and acrylates may be added in small amounts with the vinyl chloride to contribute some desirable property. Depending upon the polymerization process and the reactivity of the comonomers used the comonomer may enter the PVC chain randomly or in blocks. These VC homopolymers and copolymers are generically known as PVC resins. They are generally found in the form of powders. 10/

There are several methods of carrying out the polymerization of vinyl chloride; suspension, emulsion, solution, and bulk or mass methods. About 79% of U.S. PVC resin is produced by suspension polymerization, 13% by emulsion, 6% by bulk and 2% by solution polymerization. OSHA estimates that between five and ten thousand workers are engaged in the industries producing PVC resins. 11/

9/ American Chemical Society. Chemistry in the Economy. Washington, D.C., American Chemical Society, Oct. 1973. p.67-68.

10/ U.S. Occupational Safety and Health Administration. Final Environmental Impact Statement. p. 31-64.

11/ Ibid.

Polymerization is a batch process. Vinyl chloride monomer, as a compressed liquid, is put into a pressurized vat (110 to 160 psi) with other substances and a catalyst. Water or organic solvents may be added, or (as in bulk polymerization) the process may take place without the addition of liquids. Heat is applied (120 to 150° F) and after several hours the vat is emptied, opened and cleaned for the next batch.

The reactor kettle, or vat, is an autoclave where the reaction takes place. The usual capacity is 2,000 to 5,000 gallons but newer units hold as much as 35,000 gallons. Conversion of 85% to 90% of the monomer to polymer is considered high. Unreacted monomer is removed from the vat by vacuum for recycle to the process and the polymer is fed into a drying tower or storage tank. After the polymer is pumped out, some remains adhering to the sides of the vat. It hardens and when accumulated, lowers the heat transfer ability in the reactor. When heat transfer becomes too low, the vat must be cleaned. Older reactors are often scraped manually. But the new cleaning method is composed of high-pressure water and water-detergent systems. The new larger kettles are more easily cleaned by water jet and can produce larger quantities of resin between cleanings. Solvents such as tetrahydro furan, dimethyl formamide or ethylene dichloride may be used to remove baked-on polymer and absorb unreacted monomer. But then the solvent must be recovered and recycled. The unreacted VCM is pumped out of the vat and recovered by a series of secondary tanks containing compressors and condensers. The polymerized resin or the "slurry" is removed to tertiary tanks, dewatered in a centrifuge, and dried with a stream of hot air in a rotary dryer. 12/ 13/

12/ Ibid.

13/ U.S. Occupational Safety and Health Administration. Hearing Before Administrative Law Judge Myatt. Engineering and Control Practices. Testimony of K.H. Oelfke of the DOW Chemical Co., Freeport, Texas, July 8-11, 1974.

After polymerization, PVC resins are compounded with additives by a variety of methods. Additives to PVC may include thermal stabilizers to prevent the loss of hydrogen chloride in processing, flow agents, colorants, solid fillers, rubbers to improve low-temperature properties and plasticizers, which are needed in quantities of 20% to 40% in flexible PVC films. Finally, the compounded resin undergoes a variety of processes at fabricating plants. 14/

14/ U.S. Occupational Safety and Health Administration. Final Environmental Impact Statement. p. 31-64.

V. HISTORY

The first vinyl chloride resin was discovered in 1872. Polyvinyl chloride and copolymer resins remained laboratory curiosities with no commercial applications until 1927 when E.W. Reid discovered the useful properties of copolymers made of vinyl acetate and vinyl chloride. Chemists at B.F. Goodrich Co. first learned to plasticize polymerized vinyl chloride itself into flexible forms in the mid 1930's. The first commercial vinyl plant was opened by Union Carbide in 1936. In 1940 Goodrich opened its own plant. Polyvinyl chloride (PVC) was hailed as a miracle material; cheap, stable, fire resistant and able to assume an extraordinary range of soft and hard forms. The ready availability of natural rubber, however, limited development of the PVC industry until the outbreak of World War II. During World War II interest focused on the polyvinyl chloride resins as flame proof substitutes for rubber and as corrosion-resistant coatings for naval supplies. Polyvinyl chloride plastics, although they had poor electrical insulating properties compared to polyethylene, were tough and abrasion resistant and especially useful in low voltage applications.15/ 16/

During the 1940's vinyl chloride gas was tried as a medical anaesthetic in conjunction with nitrous oxide. Doctors abandoned the attempt when it was found to produce heart arrhythmias. From the time of its discovery, vinyl chloride gas seemed virtually harmless. The only apparent dangers were of explosions at concentrations greater than 36,000 ppm, and intoxication and narcosis at levels above 6,000 ppm. Effects of chronic exposure were not suspected. No particular attention was paid to workplace ambient concentrations so long as they were below explosive levels. In 1949, a Russian group 17/ found a hepatitis-like condition in fifteen of a group of forty-

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15/ Ibid.

16/ American Chemical Society. op. cit.

17/ Tribuch et al. Hepatitis-Like Liver Changes. in U.S. Congress. Senate. Subcommittee on the Environment. Dangers of Vinyl Chloride. Hearings, 93rd Congress, 2nd Session, Washington, D.C., U.S. Government Printing Office, Aug. 21, 1974. p.13.

at polyvinyl chloride polymerization workers. At this time, levels in these plants most likely reached several thousand ppm.18/ European researchers detailed other symptoms of what came to be called 'vinyl chloride worker's disease' including skin lesions, gastritis and circulation disorders. 19/ 20/

In 1961, Torkelson and others 21/ discovered slight reversible liver injury in rats exposed seven hours per day to 100 ppm VCM and recommended that the time-weighted average (TWA) for industrial exposure not exceed 50 ppm. At about this time DOW Chemical Co. voluntarily adopted an average exposure limit of 50 ppm for its workers but government standards remained unchanged. By the late 1960's acro-osteolysis, a disease involving reversible degeneration of the finger bones was identified among workers who cleaned the polymerization vats. The etiology seemed to involve high level exposure to vinyl chloride monomer and minor trauma to the hands. 22/

In 1968 Kramer and Mutchler 23/ found that repeated exposure to vinyl chloride at 300 ppm TWA for a working lifetime could cause impairment of liver function in humans.

Weaver, P.H. On the Horns of the Vinyl Chloride Dilemma, Fortune, Oct. 1974. p. 150-151.

19/ Lee, F.I. and D.S. Harry. Angiosarcoma of the Liver in a Vinyl Chloride Worker. The Lancet, June 29, 1974. p. 1317.

20/ How Hazardous to Health is Vinyl Chloride? Journal of the American Medical Association. June 10, 1974. p. 1355.

21/ Torkelson, T.R., Oyen F. and V.K. Rowe. The Toxicity of Vinyl Chloride as Determined by Repeated Exposure of Laboratory Animals. American Industrial Hygiene Association Journal, v. 22, no. 5, 1961. p. 354-361.

22/ Cook, W.A. et al., Occupational Acroosteolysis: II, An Industrial Hygiene Study. Archives of Environmental Health, v. 22, Jan. 1971. p. 74-82.
Dinman, B.D. et al. Occupational Acroosteolysis: I, An Epidemiological Study. Archivers of Environemntal Health, v. 22, Jan. 1971. p. 83-91.
Dodson, V.N. et al. Occupational Acroosteolysis: III. A Clinical Study. Archives of Environmental Health, v. 22, Jan. 1971 p. 83-91.

23/ Kramer, C.G. and J.E. Mutchler. The Correlation of Clinical and Environmental Measurements for Workers Exposed to Vinyl Chloride. American Industrial Hygiene Association Journal, v. 33, 1972. p. 19-30.

Finally, in experiments begun in 1967, Dr. Pierluigi Viola, attempting to produce an animal model for acro-osteolysis, exposed rats to 30,000 ppm vinyl chloride and found that many developed cancers of the skin, lungs and other organs. He presented this data at the Tenth International Cancer Congress in Houston in 1970 but mentioned that he felt that this data did not necessarily apply to humans. 24/ Dr. Viola's study caused four European producers of polyvinyl chloride plastics, Montedison, Imperial Chemical Industries (ICI), Solvay and Rhone-Progil, to commission Dr. Cesare Maltoni of the Instituto di Oncologia, Bologna, Italy, to undertake a large scale animal study testing for cancer at levels approximating worker exposure.

24/ Viola, P.F. Cancerogenic Effects of Vinyl Chloride. Abstract, Tenth International Cancer Congress, (Houston, Texas), 1970. p. 1-20.

VI. THE DISCOVERY OF THE CARCOGENICITY OF VINYL CHLORIDE MONOMER

About September 5, 1971 Dr. Maltoni, in response to Dr. Viola's results, began toxicity studies in rats. He observed his first angiosarcomas in August 1972. On January 17, 1973 technical delegates of the Manufacturing Chemists Association's (MCA) VC and PVC industries visited Dr. Maltoni's facilities and learned details of his experimental procedures and results. MCA and participating U.S. Firms had promised to hold Dr. Maltoni's work confidential and not release information outside of the task group without specific consent of the European group sponsoring the study. The purposes of the restriction were "that preliminary indications not be released until they have been validated, thereby to minimize unwarrented speculation" and "that release remains subject to the control of the project's proprietors." 25/ On January 30, 1973 National Institute of Occupational Safety and Health (NIOSH) published in the Federal Register a request for information on the potential hazards associated with occupational exposure to a list of 23 chemical substances and physical agents. Among these was vinyl chloride. MCA apparently did not at this time mention Maltoni's preliminary results. The first public disclosure of these findings tooks place at the Second International Symposium on Cancer Detection and Prevention held at Bologna on April 9 to 12, 1973. At that time, during presentation of a general paper on occupational carcinogenesis, Dr. Maltoni 26/ showed a table of preliminary results with vinyl chloride which indicated cancer formation; angiosarcomas, zymbal gland (ear canal) carcinomas and nephroblastomas, at 250 ppm exposures. The impact of the paper seems to have been minimal.

At the same time several epidemiological studies of vinyl chloride workers had been initiated, in response to Dr. Viola's study. In 1971 ICI had begun such a study

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25/ Vinyl Chloride Controversy Continues. Chemical and Engineering News. June 10, 1974. p. 12.

26/ Maltoni, C. Preliminary Report on the Carcogenicity Bio-Assay of Vinyl Chloride. (presented at the Occupational Health and Safety Administration Vinyl Chloride Fact-Finding Hearing, Feb. 15, 1974.)

which was completed up to the end of 1971 and then updated to the end of 1972. This study disclosed no increase in deaths attributable to cancer among vinyl chloride workers when compared to a control group of chemical workers never exposed to VCM. On July 17, 1973 Dr. Marcus Key of NIOSH met with MCA delegates and an ICI representative from the United Kingdom, in Washington to discuss vinyl chloride. According to Dr. Key,

> "They went into some detail on the findings of Professor Viola in production of tumors of the skin, the ceruminous gland of the ear canal, lung, and bones of rats which occurred from exposure to very high concentrations.
>
> As the result of this study, we were told that a second order toxicology study was being conducted in Italy and that an epidemiological investigation had been conducted at ICI in the United Kingdom.
>
> The ICI study had turned up no human evidence of any problem with vinyl chloride.
>
> The second level animal toxicity study in Italy was also presented to us. We did not get the specifics of the study except that the concentrations of vinyl chloride were much lower and that several species of rodents had been exposed and tumors had been produced. We interpreted what was being presented to us as confirmation of Viola's previous work, especially as regards the production of cancer in the ceruminous glands of the rat's ear canal.
>
> No mention was made to us about liver cancer and the new Italian investigator was not named." 27/

According to A.W. Barned, Director of ICI Plastics Division, the ICI physician present at the meeting reported the production of primary tumors at several sites at levels lower than those of Dr. Viola's study but said that he did not construe this to mean only zymbal gland tumors and their metastases were produced. In this initial presentation, the European delegation apparently presented the animal results in a generalized form, saying that vinyl chloride apparently proved carcinogenic to rats at several sites and at levels as low as 250 ppm. Angiosarcoma, though detected, was not mentioned specifically since there was no human epidemiological evidence to indicate that this particular cancer, very rare in humans, was more important than the other cancers detected. 28/ In Britain, the United Kingdom Employment Medical Advisory

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27/ U.S. Congress. Senate. Subcommittee on the Environment. op. cit. p. 57.

28/ Barnard, A.W. ICI Ends Its Silence on Vinly Chloride. Chemical and Engineering News, July 8, 1974. p. 21 and 37.

Service and the Factory Inspectorate say they had no information on the carcogenicity of VCM, apart from Dr. Viola's paper, until January 1974.

As New Scientist put it: 29/

> It is probably impossible to say whether the chemical industry deliberately and maliciously hid unfavourable research findings (in 1973). It is, however, likely that, even if this were not the case, the results would not have caused much of a stir. For by this time, the epidemiological survey was showing negative results. ICI had found no deaths from angiosarcomas among ex-employees. Thus in January 1973 there was no human evidence of VCM's carcinogenic properties. Because extrapolating from animals about carcinogenicity is notoriously problematic, epidemiological evidence carries greater weight in the minds of industry and regulatory bodies. Thus it is unlikely that animal studies alone would have been convincing enough to force a reappraisal of industrial exposure standards. "Firm" evidence only arose after the Goodrich report, when other cases of deaths from angiosarcoma were unearthed. ICI updated its survey and found one ex-employee who died from liver cancer in 1973.

According to Dr. Key, if he had known of the induction of liver cancers in July of 1973, NIOSH "would have taken an entirely different course of action in view of the widespread use of this material (vinyl chloride)". NIOSH "would have immediately gotten together with NCI and the Food and Drug Administration (FDA), and brought in some of the best toxicologists in the country to review the data and decide what actions to take." 30/

In the spring of 1973, Dr. John L. Creech, plant physician for the B.F. Goodrich plant in Louisville, Kentucky, noting an increase in liver ailments among plant employees, initiated tests to detect liver abnormalities. In December 1973 he received a report that one of the workers had died of angiosarcoma of the liver. Remembering another death from the same cause three years earlier, he notified a superior. By January 16, 1974, B.F. Goodrich, running a systematic mortality study of workers, discovered reports of a third angiosarcoma death. On January 22, 1974, Goodrich notified NIOSH that three workers at their PVC polymerization plant had died of angiosarcoma of the liver. On January 29, 1974, further review by Goodrich turned up a

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29/ McGinty, L. Science Paused and 17 Died. New Scientist., June 15, 1974. p. 675-676.

30/ U.S. Congress. Senate. Subcommittee on the Environment. op. cit. p. 57.

fourth case in 1968. The rarity of the disease and the clustering of deaths at a single plant raised suspicions that an occupational disease related to exposure to vinyl chloride had been discovered. On January 30, 1974 an OSHA fact-finding hearing was announced. It was held on February 15, 1974. Dr. Maltoni's animal data, showing cancer in rats at levels of 250 ppm was released at the hearing. 31/ 32/ 33/

31/ Falk, H., Creech, J.L., Heath, C.W., Johnson, M.N., and M.N. Key. Hepatic Disease Among Workers at a Vinyl Chloride Polymerization Plant. Journal of the American Medical Association, v. 230, no. 1, Oct. 7, 1974. p. 59-63.

32/ Saar, J. Vinyl Chloride and Cancer. The Washington Post, May 5, 1974. p. C2.

33/ Maltoni, C. op. cit.

VII. WORKER EXPOSURE IN THE VINYL CHLORIDE INDUSTRIES

Workers are exposed in all three segments of the PVC industry, monomer production, polymerization and fabrication. The greatest exposure probably takes place in polymerization plants. 34/

Monomer production takes place as a relatively closed, continuous process and, especially in warm climates, takes place in the open air. Plants generally are highly automated. The major sources of exposure for the one thousand to 1500 workers involved in monomer production are judged to be:

1) sampling and analysis of vinyl chloride for quality control.
2) loading of vinyl chloride for shipping.
3) maintenance and repair work which necessitates entry of vinyl chloride containing vessels and
4) exposure to leaks of vinyl chloride in the processing area. Leakage possibly accounts for 40% of the total emmission from vinyl chloride and polyvinyl chloride plants. 35/ 36/

It is probable that higher levels of vinyl chloride gas are encountered by the approximately five to ten thousand workers in the PVC resin industries than by those in monomer production of fabrication. The areas of greatest exposure in the PVC industry are:

1) unloading of incoming vinyl chloride.
2) reactor cleaning.
3) entry into vinyl chloride containing vessels for maintenance and repair work.

34/ U.S. Occupational Safety and Health Administration. Final Environmental Impact Statement; Proposed Regulation, Vinyl Chloride. Washington, D.C., Sept. 5, 1974. p. 31-64.

35/ Ibid.

36/ U.S. Environmental Protection Agency. Report of the Activities and Findings of the Vinyl Chloride Task Force. Washington, D.C., Sept. 1974. p. 1-16.

4) entry into PVC storage silos.

5) shipping or packing PVC.

6) leaks of vinyl chloride in the process area.

Thirty-two out of 38 cases of occupationally related angiosarcoma in ten countries occurred in PVC polymerization workers. In most of the early PVC resin polymerization plants the vinyl chloride gas could be smelled almost constantly. This means constant exposure to levels in excess of 2000 ppm. Workers occassionally got 'high' from the fumes. It is generally agreed that during the early period of the industry, into the 1950's, exposures of several thousand ppm were common. During the 60's the ambient levels most commonly were in the range of 100 to 200 ppm with occasional excursions as high as 500 ppm, the American Conference of Government Industrial Hygienists (ACGIH) voluntary ceiling. Dow Chemicals, acting on Torkelson's data, attempted to reduce its own plant levels to below 50 ppm and by the early 1970's had achieved average exposures of about 25 ppm in its copolymer plants.37/

PVC production is labor intensive and in the colder climates it is necessary to close the plants. It has been estimated that in the United States less than half are open. Of the workers, it is likely that reactor cleaners suffer the greatest exposure. Most of the cases of angiosarcoma of the liver in polymerization workers occurred among those who had at one time been reactor cleaners. Polymer, hardened and accumulated on the walls of the reactor tank must be cleaned away to allow efficient heat transfer into the vat. High pressure water jets do the bulk of the cleaning, but in some older vats this method cannot be used. Until recently vats in most older plants were entered once or twice a day. Although the air within the reactors was replaced several times, a short burst of vinyl chloride would be released from the reactors immediately upon opening. In addition, the PVC that remained encrusted

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37/ Ibid.

n the reactor, because of its porous structure, could retain significant amounts of entrapped VCM which was released in the process of chipping and cleaning the vat. Now, the most modern equipment is entered and cleaned manually only once a month. The job is presumably less hazardous with the introduction of respirators and protective clothing. Also air is more efficiently evacuated from the vat. 38/

Approximately 350,000 workers may be exposed during the fabricating process to unreacted vinyl chloride monomer which remains trapped in the PVC resin. The levels of unreacted VCM in PVC resins are usually between 50 and 100 ppm though they may be occasionally as high as 8000 ppm. Most of this VCM is released during storage or processing, especially heat processing. The levels of VCM found in finished products are probably no higher than 5 to 20 ppm. The vast majority of workers employed in the VC-PVC industries are involved in PVC fabricating and manufacturing. Levels of exposure in many plants are probably well below 1 ppm. Levels in fabricating plants however may be as high as 12 ppm. Past levels may have been higher. Angiosarcomas of the liver have been found in workers in fabrication plants. 39/

A summary of estimated current exposure levels in PVC fabricating facilities and polymerization plants and a list of major emission sources in PVC polymerization plants and VCM production plants is found in Appendix III.

38/ Ibid.

39/ Ibid.

VIII. OTHER EXPOSURE TO VINYL CHLORIDE MONOMER

Emission

There is a material loss of vinyl chloride and polyvinyl chloride of 4 1/2% to 7 1/2% during the PVC polymerization process. Substantial amounts of vinyl chloride, probably more than 200 million pounds per year, and PVC, more than 50 million pounds per year, are being discharged into the environment during the PVC production process. Seventy-five percent of the losses are probably by vinyl chloride air emissions. The principal area of vinyl chloride leakage in PVC plants is probably associated with the operation of the polymerization kettles which are periodically opened for cleaning or for recharging or sampling. Other losses occur during transfer of vinyl chloride from tanks to storage, during the PVC drying process and at a variety of leaks in valves, flanges and pump seals. 40/

Preliminary monitoring by the Environmental Protection Agency (EPA) in the vicinity of VC and PVC resin plants indicates that levels of VC in ambient air fluctuate [illegible]ly, apparently due to periodic openings of the reactor kettles in PVC plants, variations in production processes, and meteorologic conditions. Almost all of the air samples taken by EPA at 12 PVC and VC plants contained detectable levels of VC. The overwhelming majority of those samples contained less than one ppm but there were occasional higher excursions, one instantaneous reading was as high as 33 ppm. Vinyl chloride in air probably has a reaction rate of eight to ten percent per hour. The reaction products include ozone, nitrogen dioxide, carbon monoxide, formaldehyde, formic acid and formyl chloride. Human eye irritation symptoms from exposure to vinyl chloride in air may be caused by these products. Although vinyl chloride will disappear within a few miles downwind of a vinyl chloride air emission source, near the source it may be considered a stable pollutant. 41/

40/ Ibid.

41/ Ibid.

Water effluents typically contained levels of two to three ppm, the highest level being 20 ppm. Levels seemed to be dependent on in-plant handling of waste. Levels of vinyl chloride entrapped in solid wastes and sludge ranged from 100 ppm to, in one case, 300 ppm. The EPA Task Force estimates that emissions from PVC resin plants could be cut 75% and from VCM plants, 90%, with a concomitant increase in the cost of PVC of about 4%. It is also estimated that available control technology could be implemented within a few months to two years after promulgation of a standard. If emission were cut 75% or 90% the 24 hour average concentrations would be about 90ppb. 42/

Cases of angiosarcoma of the liver have occurred among persons not directly involved with vinyl chloride occupationally but who did live in the vicinity of VC-PVC plants. Emissions from these plants may therefore pose a health hazard. 43/

There is a close relationship between the EPA standard for emission and the allowable levels of vinyl chloride in the workplace. EPA and OSHA are working closely together to assure compatibility of standards. EPA is supporting toxicological studies to determine the effects of vinyl chloride on the developing fetus and its interaction with other carcinogens. EPA is also planning epidemiological studies of population living near a PVC plant. EPA will continue monitoring possible air emission sources and drinking water supplies possibly contaminated with vinyl chloride from emission sources or from vinyl chloride migration out of PVC pipe and storage tanks. EPA will also investigate solid waste disposal of PVC plants, especially leachates from land disposal and incineration of PVC products. 44/ Also EPA will concern itself with the effect of vinyl chloride monomer and tars from vinyl chloride plants on aquatic life and other wildlife.

42/ Ibid., p. 31-32.

43/ U.S. Center for Disease Control. Cancer and Birth Defects Division. Bureau of Epidemiology. Internal Report on Cases of Angiosarcoma of the Liver in Connecticut. Oct. 9, 1974.

44/ U.S. Environmental Protection Agency. op. cit. p. 63-65.

Aerosols

In response to a petition by a consumer advocate organization, the Health Research Group, EPA has banned indoor pesticides using VCM as a propellant; the Consumer Product Safety Commission (CPSC) has banned its use in household products; and the Federal Drug Administration (FDA) has banned it from use as a propellant in cosmetics and has stated that its use in drugs requires a New Drug Application. Vinyl chloride was never used in aerosol foods. Preliminary tests at EPA 45/ research facilities shows that a 30 second release of an aerosol containing vinyl chloride could result in a concentration as high as 400 ppm in air. Related tests showed that in closed rooms vinyl chloride will persist for many hours and, even when diluted by ventilation will probably result in some vinyl chloride exposure for several hours. Cosmeticians and other groups who may have used large quantities of aerosols in enclosed spaces may have received significant exposure to vinyl chloride. The effect of the low levels the general public has been exposed to is not known.

Transport Accidents

More than two-thirds of the vinyl chloride monomer produced is transported to PVC resin plants located at another site. 95% of the transport is done by rail. During the last three years there have been 16 reported rail accidents involving vinyl chloride tank cars. The amount of vinyl chloride that persons in the vicinity may have been exposed to at these times and the effects of single large doses of vinyl chloride are not known.

Finished Products

Finished PVC products probably contain levels of unreacted VCM of 5 to 20 ppm. The VCM may be released slowly upon storage presenting a possible hazard to warehouse personnel. It may be released when the finished products are disposed of and incinerated.

45 / Ibid. p. 32.

PVC pipes and liners are used in many water supply systems. Little is known about the extent or effect of possible PVC migration from there into drinking water. PVC wrappings used for food may also allow migration of small amounts of VCM into food products. The extent of this and the possible effects on the population are being investigated by FDA. Meat wrappers who use a heat source to cut PVC wrapping may develop 'meat wrappers syndrome'. This is a respiratory problem. It might be caused by hydrochloric acid, VCM, or some other PVC degeneration product. OSHA and NIOSH are presently investigating this problem.

PVC packaging for food and drugs was introduced in the 1940's and was in use before the enactment of the Food Additives Amendment of 1958. Therefore, it was not tested for toxicity as more recent additives have been. FDA will set up an interim level of allowable VCM migrating into food from PVC wrapping under Code of Federal Regulation 121.4000 pending an investigation of the carcogenicity of VCM by the oral route. The final proposal for an interim standard may be based upon a particular allowable level of VCM migration from the PVC packaging rather than upon VCM residual levels in the PVC. The Society of the Plastics Industry has suggested a level of 50 ppb. Methods have been developed to detect vinyl chloride in foods in that quantity. One of the problems with a standard of migration of VCM is the difficulty in measuring lower amounts of VCM in food. FDA studies have indicated that a reading of 50 ppb is the lowest that can be reported with confidence. 46 / Use of PVC in cosmetic and drug containers will probably follow the same standards as those the Bureau of Foods sets for food wraps. 47 /

The use of PVC in blood bags is one particular case where substitutes are held to be inadequate. The only possible substitute is to return to the use of glass.

46/ PVC Interim Regulation Based on UCM Extraction Previewed Food.Chemical News, Jan. 20, 1975. p. 33-35.

47/ Second Thoughts on Using PVC. Chemical Week, July 31, 1974. p. 19-20.

This would require complete redesign of facilities. It has also been suggested that the increased safety of PVC may make its use advantageous even if small amounts of VCM are present. 48/

48/ Food and Drug Administration, Bureau of Foods. Personal Communication.

IX. EPIDEMIOLOGY

As of January 16, 1975, 38 cases of angiosarcoma of the liver among workers exposed to vinyl chloride had been reported from ten countries. The median age at diagnosis of angiosarcoma of the liver for all known occupational cases is 45 years with a range of from 36 to 71 years. The median interval from first exposure to vinyl chloride to detection and diagnosis of angiosarcoma is 18 years with a range of from 6 to 30 years. The shortest exposure time is 3 years. See Table I.

Two other cases of angiosarcoma of the liver occurred in persons who had no occupational exposure to vinyl chloride but who had lived within 1/2 mile of a plastics factory for 35 years and within 2 miles of an electrical products plant for more than 50 years. One case of hepatoma, not angiosarcoma, was diagnosed in 1971 in the young daughter of a PVC worker. However, hepatoma is a common lesion and occurs in perhaps 16% of all childhood tumors. Therefore it may well be unrelated to any possible vinyl chloride exposure. 49/

There is some question whether exposure to vinyl chloride specifically induces only angiosarcoma of the liver or whether it increases the rate of incidence of other more common cancers as well, as is the case in animals. Tabershaw and Gaffey 50/, in a study of 8383 men, including 352 death records, who had at least one year of occupational exposure to vinyl chloride, gave evidence that vinyl chloride may possibly be involved not only with angiosarcoma of the liver but also with cancers of other sites. Cancers of the respiratory system, brain and of unknown site and lymphomas occurred very slightly more often than expected in those members of the study population with the greatest estimated exposure. Criticisms of this study, and

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49/ U.S. Center for Disease Control. op.cit.

50/ Tabershaw, I.R. and W.R. Gaffey. Mortality Study of Workers in the Manufacture of Vinyl Chloride and its Polymers. Journal of Occupational Medicine, v.16, no.8, Aug. 1974. p.509.

TABLE I - Reported Cases of Liver Angiosarcoma in Workers Exposed to Vinyl Chloride or Polyvinyl Chloride 51/

Country	Case No.	Birth Date	First VC or PVC Exposure	Diagnosis of angio-sarcoma	Age at Diag.	Years Since First Exposure	Total Years Exposure	Date of Death
			Polymerization Workers					
Canada	01							
Canada	02							
Canada	03							
Canada	04							
Czechoslovakia	01		Awaiting					
Czechoslovakia	02		Details					
France	01	-	-	-	43	19	19	00-00-67
Great Britain	01*	00-00-01	00-00-46	12-00-72	71	26	20	12-00-72
Great Britain	03	06-00-37	02-00-66	-	38	8	4	-
Italy	02	11-13-29	00-00-57	12-12-72	43	15	6	12-00-72
Norway	01*	12-23-15	03-00-50	12-20-71	56	22	21	01-04-72
Rumania	01	Awaiting Details						
Sweden	01*	06-23-27	08-14-51	02-00-70	43	19	18	10-20-70
United States	01*	10-17-23	12-09-48	03-03-73	49	22	16	03-03-73
United States	02*	08-19-33	11-15-55	05-00-70	36	14	13	09-28-71
United States	03*	05-25-15	11-28-45	12-19-73	58	28	28	12-19-73
United States	04*	01-15-24	07-06-52	08-19-67	43	15	15	01-07-68
United States	05*	01-25-12	06-19-44	04-09-64	52	20	18	04-09-64
United States	06*	00-00-29	01-17-62	02-00-74	45	12	12	Alive
United States	07*	05-03-22	08-00-44	00-00-68	45	24	18	03-23-68
United States	08*	05-06-20	10-07-46	08-00-61	41	15	15	08-29-61
United States	09*	00-00-31	05-28-45	03-01-74	43	29	17	Alive
United States	10*	08-16-13	06-12-51	05-00-68	55	17	17	05-10-68
United States	11*	05-27-09	10-14-46	03-00-70	61	23	23	03-16-70
United States	12*	11-17-18	09-13-49	05-02-69	50	20	15	05-02-69
United States	13*	12-01-21	08-19-44	05-00-74	53	30	30	07-04-74
United States	16*	11-04-27	05-08-50	00-00-69	41	17	4	03-27-69
United States	17	05-06-31	06-23-55	10-11-74	43	19	19	Alive

51/ U.S. National Institute of Occupational Health and Safety, Dr. Heath, Personnel Communication.

TABLE I - Reported Cases of Liver Angiosarcoma in Workers Exposed to Vinyl Chloride or Polyvinyl Chloride 51/

Country	Case No.	Birth Date	First VC or PVC Exposure	Diagnosis of angio-sarcoma	Age at Diag.	Years Since First Exposure	Total Years Exposure	Date of Death	
Polymerization Workers, cont.									
West Germany	01	07-26-31	10-14-57	00-00-71	40	14	14	12-14-71	
West Germany	02	06-04-30	10-01-57	00-00-69	39	11	11	01-25-69	
West Germany	04	-	-	-	44	17	-	-	
West Germany	05	-	-	-	49	11	-	Alive	
Compounders, Fabricators, and V.C. Polymerization Workers									
Great Britain	02*	09-08-14	00-00-46	02-00-70	55	24	11	12-00-70	Note 1
Italy	01	06-15-34	00-00-65	04-19-71	36	6	3	04-16-71	Note 6
Sweden	02*	11-27-11	00-00-45	05-15-72	61	27	23	00-16-72	Note 7
United States	14	00-00-13	08-18-38	06-00-73	60	35	00	07-03-73	Note 2 & 5
United States	15*	00-00-25	00-00-00	07-00-72	47	00	00	02-15-73	Note 3
West Germany	03	00-00-00	00-00-00	00-00-00	43	14	00	00-00-00	Note 4

Note 1 Pouring PVC oil mixture onto fabric bases
Note 2 Machine operator covering electrical wire with PVC plastic insulation
Note 3 Accountant at several fabrication plants (work history under review)
Note 4 Loading pesticide cans with VC propellant
Note 5 Diagnosis: Sarcoma (possibly "angiosarcoma"), liver. Possibility of generalized neoplasm of the reticuloendothelial cell system cannot be ruled out.
Note 6 Worked for producer of PVC sacks. Had angiosarcoma of several sites.
Note 7 VCM worker

* Indicates microscopically confirmed angiosarcoma of the liver.
"00" Indicates unknown data.

the relatively small increase in cancer mortality it shows, have been made on the basis of the fact that workers with long exposure and long latency periods since first exposure are inadequately represented in the study.

Monson and others 52/, in a study of 161 deceased workers, found a 50% excess of observed versus expected deaths due to all cancers with the greatest specific excesses including cancer of the liver, biliary tract, lung and brain.

Epidemiological studies carried on at the Dow Chemical plant in Midland, Michigan indicate in a very preliminary way that the vinyl-chloride-induced increase in some cancers may be reduced in populations exposed to less than 200 ppm TWA. No data on angiosarcomas is available. 53/

NIOSH - Center for Disease Control (CDC), in a study of 930 workers, including 109 death records, who had achieved five or more years of employment and ten years since onset of initial employment, found a 57% increase in deaths due to cancer. This apparent increase is "not limited to any single organ system. An excess cancer mortality was observed for the respiratory system, the blood forming tissues and the brain and central nervous system." The number of deaths from liver cancer in this population was almost twelve times the number expected. Strikingly, the majority of these excess cancer deaths did not occur until 15 or more years after first exposure to vinyl chloride. This latent period is consistent with other observations on occupational cancer. 54/

Dr. Thomas Mancuso of the University of Pittsburgh, School of Public Health, pointed out that vinyl chloride is a possible "index carcinogen" for a whole group

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52/ Monson, R.R., Peters, J.M. and M.N. Johnson. Proportional Mortality Among Vinyl Chloride Workers. The Lancet, Aug. 17, 1974. p. 397-398.

53/ U.S. Occupational Safety and Health Administration. Hearing before Administrative Law Judge Myatt. Testimony by B.B. Holder of the Dow Chemical Co., Midland, Michigan.

54/ U.S. Congress, Senate. Subcommittee on the Environment. op. cit. p.59.

of similarly structured chemicals. The chance recognition of vinyl chloride brought about because it causes a rare form of cancer will, he hopes, lead to a comprehensive national study of industrial cancers. OSHA is investigating indications which came from chemical manufacturers of a possible link between vinylidene chloride, one of the PVC copolymers, and cancer. 55/ Studies by Dr. Viola show the development of abdominal tumors at 200 ppm of vinylidene chloride in animals.

The effects of vinyl chloride appear to have had a long latent period. This means that the relatively low numbers of deaths to date may, as Anthony Mazzocchi of the Oil, Chemical and Atomic Workers put it, "be only the tip of the iceberg" as far as the future effects of past vinyl chloride exposure is concerned.

55/Vinylidene Chloride: New Cancer Threat? Job Safety and Health, Dec. 1974. p.2.

X. ANIMAL DATA ON THE HEALTH EFFECTS OF VINYL CHLORIDE

Dr. P.L. Viola reported at the Tenth International Cancer Congress his observations of malignant tumors in the ear canals (zymbal glands) of rats exposed to 30,000 ppm vinyl chloride for four hours per day, five days per week. He also reported tumors in the lungs and bones of the rats. In the United States on May 5 and 6, 1971, he gave a more detailed report to the MCA noting that he had observed tumors at levels of 5,000 ppm.56/ Dr. Maltoni's studies, by February of 1974, uncovered the formation of tumors in animals exposed to 250 ppm vinyl chloride. In May he reported tumors produced at 50 ppm.

Bio-Test Laboratories in Decatur, Illinois, under a contract with the MCA began animal tests February 1, 1973.57/ Three species of animals, albino mouse, albino rat, and golden hamster, were used. Tumors were developed in all three species. As of August 14, 1974 the hamsters had developed tumors only upon exposure to 2,500 ppm. But both mice and rats had developed tumors at 50 ppm. Tumors were found in the liver, lung, kidney and mammary gland. Both Bio-Test Laboratories and Dr. Maltoni have demonstrated that the tumors are to some extent dose-related. That is, more tumors occur at higher levels. Whether vinyl chloride would continue to cause tumors, though proportionally fewer and fewer tumors per exposed population, as the level of exposure dropped or whether investigators could eventually designate some level of vinyl chloride as a "no effect" level, below which vinyl chloride is not carcinogenic in animals, remains to be seen. At the present, tests have not been completed at levels below 50 ppm so the carcinogenicity of these low levels has not been determined. Studies are presently underway to determine the teratogenic (birth defect) effects of vinyl chloride, if any. 58/

56/ Viola, P.L., Bigotti, A., and A. Caputo. Oconogenic Response of Rat Skin. Lungs, and Bones to Vinyl Chloride. Cancer Research, v. 31. p. 516-581.

57/ Industrial Bio-Test Laboratories, Inc. Decatur Research, 1800 East Pershing Road, Decatur, Illinois, 62526. Communication to Dr. K.D. Johnson of MCA, August 16,1974.

58/ Schetz et al. Preliminary Report: Vinyl Chloride Teratology in Mice, Rats and Rabbits. Unpublished data.

XI. HUMAN HEALTH EFFECTS OF VINYL CHLORIDE

Angiosarcoma of the Liver

Primary cancer of the liver is uncommon in the United States, and primary carcinoma of mesodermal origin is extremely rare. About 25 instances of angiosarcoma of the liver are normally found in a year in the entire U.S. population. Because of this, angiosarcoma is a difficult diagnostic problem. Many are recognized only upon autopsy.

Initial clinical symptoms vary widely and include weakness and tiredness, pronounced weight loss and enlargement of the liver. About two-thirds of all carcinomas of the liver have a clinical onset characterized by indefinite abdominal symptoms which are usually attributed to gastric disturbances, sometimes gastric ulcer. The liver symptoms are generally indicative of cirrhosis. Some patients, when detected, were asymptomatic.

In adults, carcinoma of the liver, if untreated, is uniformly fatal within six months. Carcinoma of the liver can be cured only by surgical excision and this is possible only when the lesion is small and well localized. Chemotherapeutic agents and radiation therapy are of palliative value only.

It may be that there is considerable variation in susceptibility to the hepatic effects of vinyl chloride. Heavy alcohol intake renders workers more susceptible to the effects of carbon tetrachloride, for instance.

In some of the PVC angiosarcoma cases non-malignant hepatic lesions, sinusoidal dilation, and atypical sinusoidal lining cells coexisted with the cancer. Conceivably such lesions may represent a precursor stage in development of the angiosarcoma and might aid in early detection. Cases of angiosarcoma do not seem to be typically preceeded by acro-osteolysis.

Angiosarcoma of the liver is also proved to be caused in humans by exposure to arsenic and to Thorotrast, a radioactive material in the form of colloidal thorium dioxide used in cerebral vessel visualization between 1930 and 1947. 59/ 60/

Acro-osteolysis

As early as 1957 a new occupational disease among PVC polymerization kettle cleaners was beginning to be identified. In the 1960's this syndrome first came prominantly to notice. It was wide-spread among workers, occurring in approximately one to three percent of vessel cleaners. Symptoms included soreness and thickening of the skin of the finger tips, gradual dissolution of the calcium of the bones of the fingers and toes, skin sores and sometimes heightened sensitivity of the hands to cold, including blanching or cyanosis of the skin (Raynaud's phenomenon), and pain. The bone lesions in the distal phalanges of the fingers were associated with striking changes in the vascular system. Hepatomegaly (enlargement of the liver) was also observed. The condition was apparently self-limiting, there being considerable improvement in skin and vascular changes when the patient left the manufacturing complex. 61/ 62/

Vinyl Chloride Worker's Disease

Exposure to vinyl chloride for long periods of time has been shown to produce in some workers one or more of a constellation of symptoms that have been designated

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59/ Lee, F.I. and D.S. Harry. Angiosarcoma of the Liver in a Vinyl Chloride Worker. The Lancet, June 29, 1974. p. 1317.

60/ Interagency Collaborative Group on Environmental Carcinogens. Meeting Held April 17, 1974. Transcript.

61/ Dinman, B.D. et al. op. cit.
Dodson, V.N. et al. op. cit.
Cook, W.A. et al. op. cit.

62/ Wilson, R.H. et al. Occupational Acroosteolysis: Report of 31 cases. Journal of the American Medical Association, v. 201, 1967. p. 577-581.

"vinyl chloride worker's disease." Reported symptoms include: blood changes such as slight to moderate lessening in the number of circulating platelets, production of excessive numbers of immature red blood cells, and circulatory disturbances of the Raynaud type, enlargement of the spleen, pain in the upper abdomen, nervous system lesions, impotence and hormonal imbalances, pulmonary lesions and changes in liver anatomy and function. The lung changes may be caused by exposure to PVC dust rather than to vinyl chloride itself. Liver changes include enlargement and tenderness of the liver apparent upon palpation, abnormal liver function tests, fibrosis of the liver, detectable by biopsy or by peritoneoscopy, and portal hypertension. The surface of the liver, upon biopsy, may be seen to be covered with highly characteristic rice-grain sized nodules of surface fibrosis. The liver changes seem to conform to some extent to Banti's syndrome, and may thus be related to portal hypertension, at least in part. The liver damage may persist for up to two and a half years after the vinyl chloride worker has been removed from exposure, but much of the damage seems to be reversible. Whether the changes in the liver in some cases are indicative of a pre-cancer state has not been determined. 63/

Selikoff and others 64/ found that splenomegaly was more common in workers with longer, more than five years, experience, but that a higher percentage of abnormal liver function tests were found in workers with current exposure.

Mutagenesis and Teratogenesis

Rannug and others in Sweden, in a standard salmonella biotransformation test system showed that vinyl chloride is mutagenic. 65/ Dr. Selikoff, examining chromosomes

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63/ Falk, H., et al. cop. cit.

64/ U.S. Congress. Senate. Subcommittee on the Environment. op. cit. p. 9.

65/ Ibid. p. 32.

of 11 vinyl chloride workers has shown chromosome changes to be present considerably more often than would be expected. 66/ Finally, Dr. Infante, in epidemiological studies, has shown that there is a possibility that persons who may be exposed to environmental vinyl chloride in the vicinity of VC-PVC plants may have a higher rate of birth defects. 67/ These data are very preliminary. Dr. Maltoni's experiments 68/ also show that pregnant rats exposed to vinyl chloride may have offspring which develop angiosarcomas. The mutagenic and teratogenic potential of vinyl chloride has not, of course, been proven, but preliminary tests have certainly indicated that this is an area that should be explored further. Such considerations also make exposure of pregnant women or women at risk of pregnancy to vinyl chloride a special concern.

66/ Ibid. p. 27.

67/ Dr. Infante. Personnel Communication.

68/ Maltoni, C., and G. Lefemine. Carcigenicity Bio-Assay of Vinyl Chloride: Current Results. Annals of the New York Academy of Sciences, v. 246. Jan. 31, 1975. p. 195-218. (in print).

XII. THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION STANDARD

The Occupational Safety and Health Administration (OSHA) standard sets an exposure limit of 1 ppm averaged over any eight hour period and a ceiling of 5 ppm averaged over any period not exceeding 15 minutes. This standard applies to the entire vinyl chloride industry, VCM and PVC producers and fabricators but, where monitoring shows that no employee is exposed to levels over 0.5 ppm TWA, as is the case presently in many fabricating plants, the employer will be below the "action level" and exempted from many provisions of the standard such as medical surveillance and continual remonitoring. Where levels of VCM exceed the permissible level the use of respirators is required. 69/ 70/ 71/ Medical surveillance of employees, and retention of records of exposure and medical examination for more than 30 years are required. The standard was ordered to go into effect January 1, 1975. Until January 1, 1976, however, though employers must provide respirators, if VCM remains below a 25 ppm ceiling, the employee may decline to wear them. 72/

For current occupational exposure limits for VCM in nine foreign countries see Appendix IV.

69/ 39 FR 45012

70/ U.S. National Institute of Occupational Safety and Health. An Evaluation of Organic Vapor Respirator Cartridges and Canisters Against Vinyl Chloride. Washington, D.C., 1974.

71/ For a general review of respiratory protection see Stellman, J.N. and S.M. Daum. Work is Dangerous to Your Health. New York, Vintage Books, 1973. p. 306-326.

72/ 39 Fed. Reg. 35890. (1974).

XIII. FEASIBILITY OF THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION STANDARD

There is little dispute by government and industrial experts that PVC fabricating plants can reach a level of 1 ppm in ambient workplace air with little difficulty or economic disruption. However, industry representatives have contended that the imposition of a 1 ppm level standard for VCM producers and PVC resin industries is technically impossible. Enforcement of such a standard, they claim, would cause shutdown of PVC plants in the United States, eliminate 1.7 to 2.2 million PVC related jobs, and result in a loss of production valued at $65 to $90 billion dollars per year. 73/

Foster D. Snell, Inc., an independent consultant company, in their report to OSHA, concluded that "acheiving no detectable levels ... is judged not feasible, both in PVC and VCM sectors." The Snell study offers several reasons for concluding that the standard is infeasible: technology to eliminate VCM leaks and fugitive losses does not exist, existing plants have not been designed to operate at no detectable VCM level, ere is no operating experience in operating at very low VCM levels, there are no technology transfer opportunities to aid in design of new plants and, t cause PVC manufacture is a batch process, it could not be made emission-free. The Snell study estimated the cost, time needed for implementation and danger to the economic life of the industry as shown in Table II. 74/ Both the Society of Plastics Industries and the Snell study are in agreement that control of emissions from VCM plants will be relatively easier.

73/ Putting VCM Emissions on Skids. Chemical Week, Sept. 18, 1974. p. 67 and 71.

74/ Showdown on Vinyl Plant Rule Presages Shutdown. Chemical Week, Sept. 25, 1974. p. 15.

Table II

Foster D. Snell, Inc. Report on

OSHA's vinyl standards impact: higher costs, fewer plants

oosed VCM sure standard* (ppm.) unit	Time-weighted average	Increase in average unit costs (cents/lb.) Direct	Loss of productivity	Total[1]	Time needed to comply (months)	Proportion of industry endangered[2]
ver plants						
	15	0.04	0.03	0.07 ± 10%	0	0%
	15	0.09	0.03	0.12 ± 40%	24	0%
	2-5	0.17	0.15	0.32 ± 40%	36	0%
tectable amount"		–	–		Not feasible	100%
w plants						
	=	0.19	0.35	0.54 ± 20%	0-6	Negligible
0	15-25	0.36	0.49	0.85 ± 35%	30	4%
5	10-15	0.90	0.70	1.60 ± 50%	30	26%
tectable amount"		4.01[3]	3.07[3]	7.08 ± 75%[3]	30-48[3]	100%

chloride monomer (VCM) content, expressed as parts per million, in the air to which vees are exposed. [1] With estimated range of variance for individual plants, based on statistical analysis of data. [2] Percentage of capacity that management would seriously or shutting down. [3] Based on Firestone's estimates; actual compliance is not considered a. Source: Foster D. Snell, Inc.

col of VCM emission in PVC resin production, according to Walter ajor trouble spots are at four primary points in the manufacturing y olding tanks, 2) dryer, 3) reactor (during routine cleaning , 4) recovery systems for process vent gases."75/ The largest be cleaning the humid, VCM filled air that has been used in drying e amounts of air must be used, 40,000 cu. ft. / minute, for example. ld be solved if the VCM were removed from the slurry before it r. Alternatively, this air might be dehydrated and recycled. Equip- is available, but very expensive.

iques for controlling VCM emissions are presently under investigation. is adsorption of VCM from vent gases by activated carbon with re- e mon mer by steam or the final vent gas streams from emission sources rated to remove most of the remaining VCM. Such methods could possibly

I Emissions on Skids. op. cit. p. 66.

i ve levels of 5 ppm according to Tenneco Chemicals. Another process developed by Robin-Tech (Ft. Worth) is called Rocor IKC (in-kettle compound). It is in the process f being patented. The process combines two commonly used steps, resin making and incorporation of additives. The company claims that PVC made by this process virtually eliminates exposure of workers to VCM in the fabrication process. Companies are also looking into the possibility that the polymerization process may be driven more nearly to completion, thus easing the problem of down-stream clean-up. Another possibility is the remote peration of plants. Separation of control areas from reactor areas, while decreasing the on-the-spot ability to deal with emergencies, would decrease worker exposure.76/

"Tenneco has licensed a new PVC process which, in theory, should allow no film deposits on reactor walls. Consequently it is hoped reactors will not need to be opened on a routine basis in the Tenneco plant now being built in Pasadena, Texas." Dow, in its three monomer plants in Texas has instituted a series of procedures including magnetic leading gauges for tank cars rather than venting gas, reintroduction to the closed system of gases removed for sampling rather than release to the atmosphere and use of inert gases to purge any part of the system that must be opened.77/

There are readily available substitutes for PVC in some products, more expensive substitutes for others and no substitutes at all for still others.78/ Glass, polyethylene, polyvinylidene chloride, and other substitute materials could be used for containers, food wraps and packaging, in some cases, in place of PVC. According to Ralph L. Harding, President of the Society of the Plastics Industry (SPI): 79/

76/ Ibid.

77/ Glack, G. The Best Available Evidence. Job Safety and Health, v. 3, no. 1. Jan. 1975. p. 12.

78/ U.S. Environmental Protection Agency. op. cit. p. 1-5.

79/ U.S. Congress. Senate. Subcommittee on the Environment. op. cit. p. 95.

t [redacted]d take a minimum of three to five years to come up with a replace-
su[redacted]ting material" for wires and cables. "PVC is regarded as having no
qual as a sealant for bridges and airport construction.....The PVC belting
y has similarly stated there is no known subatitute for conveyor belting
om PVC."

environmental impact statement suggests that "in the long run U.S. companies
t profitable to build plants abroad." The OSHA final standard states "We
he PVC and VCM establishments will not be able to attain a 1 ppm TWA level
classifications in the near future. We do believe, however, that they will,
able to attain levels of 1 ppm TWA for most job classifications most of the
apparent that reaching such levels may require some new technology and
es. It may also be necessary to utilize technology presently used in other
80/ According to the petition filed by the SPI before the United States
eals there is no evidence to support the technological feasibility of ever
e exposure limits set by OSHA's final standard and the real effect of adop-
standard will be to compel full-time use of respirators by the work force
self, will be detrimental to employee health. 81/ On October 1, 1974 SPI
d[redacted]l review of the OSHA standard before the U.S. Court of Appeals. On
1974 they asked OSHA to postpone the effective date of the standard and
l. On December 3, 1974 SPI asked the U.S. Court of Appeals to stay the
ending the decision of the court, and on December 13, 1975 the Court of
ted a stay of the OSHA order. 82/

Reg. 35890. (1974).

urt of Appeals for the Second Circuit. Brief for the Petitioner: The
/ of the Plastics Industry, Inc. versus the Occupational Safety and Health
stration. (Case no. 74-2284) Washington, D.C., Bryon S. Adams Printing,
Nov. 12, 1974.

s Corner. Journal of Commerce, Dec. 5, 1974. p. 8.

APPENDIX I: CHRONOLOGY OF EVENTS

1946	American Conference of Governmental Industrial Hygienists establishes occupational exposure limit of 500 ppm for vinyl chloride in workplace air.
1949	A Russian group finds 15 of a group of 48 PVC workers with a hepatitis-like condition.
1961	Torkelson et al. discover slight reversible liver injury to rats exposed seven hours per day to 100 ppm.. He recommends that the TWA of VCM not exceed 50 ppm.
1968	Kramer and Mutchler suggest that repeated exposure to VCM at 300 ppm TWA for a working lifetime can cause impairment of liver function, but no overt clinical disease in humans.
1970	ACGIH proposes lowering VCM exposure limit to 200 ppm because of liver toxicity studies. This action affirmed in 1972. OSHA level under the Occupational Health and Safety Act remains 500 ppm.
May 22-29, 1971	Dr. Viola, at the Tenth International Cancer Congress describes observations of malignant tumors in the zymbal glands, skin, and lungs of rats subjected to levels of 30,000 ppm VCM.
Jan. 30, 1973	NIOSH publishes in the Federal Register a request for information on the hazards associated with vinyl chloride and other substances from its 1972 priority list.
Spring, 1973	B.F. Goodrich initiates liver tests on its VC industry workers.
May, 1973	Dow Chemical warns its monomer customers not to use VCM in aerosols.
May 9, 1973	FDA proposes rulemaking prohibiting the packaging of alcoholic foods in PVC because of leached VCM. Publishes notice in the Federal Register May 17.
Fall, 1973	B.F. Goodrich finds 55 out of 271 tested workers show apparent liver abnormalities.
Jan. 22, 1974	NIOSH is notified by B.F. Goodrich of three angiosarcoma deaths in the Goodrich plant in Kentucky.
Jan. 24, 1974	NIOSH - CDC conduct onsite inspection of the Kentucky Goodrich plant.
Jan. 30, 1974	OSHA fact-finding hearing is announced.
Feb. 1, 1974	NIOSH - CDC holds a briefing for Federal agencies concerned about VCM.
Feb. 15, 1974	The OSHA informal fact-finding hearing on the possible hazards of vinyl chloride manufacture and use was held.
Feb. 21, 1974	Health Research Group, a Washington-based consumer action organization, petitions Consumer Product Safety Commission (SPSC) to prohibit continued use of household products containing VCM as a propellant and to remove

	VCM containing products from the market; FDA to ban and name cosmetics with VCM; and EPA to suspend the use of pesticides containing VCM.
Mar. 11, 1974	NIOSH publishes a recommended occupational health standard for VCM at no detectable level.
Mar. 28, 1974	EPA asks for a voluntary ban of VCM in pesticides.
Apr. 3, 1974	Recall by FDA of cosmetics containing VCM.
Apr. 5, 1974	OSHA sets an Emergency Temporary Standard for VCM in air at 50 ppm. At this time no angiosarcomas had been found in animals at levels below 250 ppm. (39 FR 12341).
Apr. 15, 1974	Industrial Bio-Test Labs presents data showing animal cancer at 50 ppm.
Apr. 17, 1974	EPA releases the names of some pesticides containing VCM.
Apr. 22, 1974	FDA requests a list of all marketed drug products containing VCM as a propellant or packaged in PVC. (39 FR 14238).
Apr. 22, 1974	FDA publishes a notice of proposed amendment to the Food, Drug and Cosmetic Act concerning the use of VCM as an ingredient of aerosol drugs and cosmetics. Drugs containing VCM or packaged in PVC will require a New Drug Application. (39 FR 14215).
Apr. 24, 1974	OSHA publishes notice of an intent to file an environmental impact statement of the proposed occupational VCM standard. (39 FR 14522).
Apr. 26, 1974	EPA gives notice of an emergency suspension of the sale of pesticides containing VCM and an intent to cancel registration of the use of VCM in indoor pesticide sprays. (39 FR 14753).
April and May, 1974	EPA carries out initial monitoring of the emission of VCM by twelve VCM and PVC plants.
May 7, 1974	CPSC requests information on which aerosol products contain VCM and on possible hazards of these products. (39 FR 16511).
May 8, 1974	AFL-CIO Industrial Union Department petitions OSHA for amendment of the Emergency Temporary Standard to be lowered to no detectable concentration.
May 10, 1974	OSHA prints notice of proposal to reduce the limit of occupational exposure to VCM to "no detectable level" or 1 ppm plus or minus 0.5 ppm. (39 FR 16896).
May 10 and 11, 1974	New York Academy of Sciences with the American Cancer Society holds a symposium on VCM sponsored by NIOSH and NIEHS. Among others, Dr. C. Maltoni gives data.
May 23, 1974	CPSC prints notice of proposal to ban household aerosols containing VCM. (39 FR 18115).

May 24, 1974	OSHA gives notice of a public hearing on VCM (39 FR 18303).
May 31, 1974	EPA requests manufacturers of VCM and PVC resins to provide detailed technical and economic information concerning steps that have been and could be taken to reduce VCM emissions, under section 114 of the Clean Air Act.
June, 1974	CDC establishes nationwide surveillance registry for angiosarcoma.
June 11, 1974	The Administrator of EPA releases preliminary data from monitoring of 12 VCM and PVC plants indicating no imminent pollution hazard.
June 12, 1974	OSHA announces availability of the draft copy of the environmental impact statement. Notice published in the Federal Register June 25. (39 FR 22975).
June 24 and 25, 1974	IARC/WHO Working Group on Vinyl Chloride meets in Lyons, France to consider procedures for coordination of future international activities. NCI and NIOSH-CDC participate.
June 25 and 28 July 8 and 11, 1974	The OSHA hearing before Administrative Law Judge Myatt on the possible hazards of exposure to VCM.
July 1, 1974	EPA releases additional names of pesticides containing VCM.
July 29 and 31, 1974	The National Institute of Environmental Health Sciences holds a meeting at Pinehurst, North Carolina to assess the public health aspects of the plastics industry.
July, 1974	The Department of Transportation publishes proposals to amend the bulk dangerous cargoes regulations for carriage of VCM (39 FR 26752) and requirements for flamable protection for VCM and others (39 FR 27572).
Aug. 21, 1974	CPSC bans VCM as a hazardous substance. (39 FR 30114).
Aug. 26, 1974	FDA publishes regulations which ban the use of VCM in cosmetics and require a New Drug Application for marketing drug aerosols with VCM. (39 FR 30830).
Sept., 1974	EPA issues preliminary assessment of environmental problems associated with VCM and PVC.
Sept. 6, 1974	OSHA files final environmental impact statement. (39 FR 32350).
Sept. 13, 1974	OSHA files notice of the availability of the final economic impact statement for compliance with the proposed standard. (39 FR 33009).
Sept. 18, 1974	EPA releases a report on air and water monitoring around several VCM and PVC plants.
Oct.1, 1974	OSHA announces new regulations concerning levels of VCM in workroom air.

Oct.1, 1974	SPI asks for Judicial review of the OSHA standard before the U.S. Court of Appeals. (case no. 74-2284).
Oct. 4, 1974	OSHA publishes the Occupational Safety and Health Standard for VCM (39 FR 35890). It is a time weighted average of 1 ppm with a ceiling of 5 ppm and is scheduled to go into effect on Jan. 1, 1975.
Oct. 11, 1974	CPSC denies requests by manufacturers for a hearing on the classification of VCM as a banned hazardous substance and more specifically of the order to repurchase VCM containing aerosols. (39 FR 36576).
Nov. 5, 1974	SPI requests OSHA to postpone the effective date of the standard.
Nov. 12, 1974	SPI files a brief in the U.S. Court of Appeals of the Ninth Circuit against OSHA for review of the OSHA standard.
Dec. 3, 1974	SPI asks the U.S. Court of Appeals of the Second Circuit to stay the implementation of the OSHA order pending the decision of the court.
Dec. 13, 1974	The U.S. Court of Appeals for the Ninth Circuit stays that portion of the order of the CPSC ban on VCM aerosols requiring manufacturers to repurchase their products.
Dec. 13, 1974	The U.S. Court of Appeals of the Second Circuit grants SPI a stay of the OSHA order.
Jan. 1, 1975	The OSHA standard did not go into effect because of the Court action.

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PART II

DEPARTMENT OF LABOR

Occupational Safety And Health Administration

■

EXPOSURE TO VINYL CHLORIDE

Occupational Safety and Health Standards

Title 29—Labor

APTER XVII—OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, DEPARTMENT OF LABOR

ART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

tandard for Exposure to Vinyl Chloride

ursuant to sections 6(b), 6(c), and) of the Occupational Safety and alth Act of 1970 (84 Stat. 1593, 1596, 9; 29 U.S.C. 655, 657), Secretary of or's Order No. 12-71 (36 FR 8754) 29 CFR Part 1911, § 1910.93 of Part 0 of Title 29, Code of Federal Regulons is hereby amended in the manner forth below, in order to provide an upational Safety and Health standdealing with the exposure of emyees to vinyl chloride.

. *Background*—(1) *Vinyl chloride.* yl chloride (chloroethene). Chemical stracts Service Registry No. 75014, is a thetic organic chemical made from ylene or acetylene and chlorine by any several processes. It is the parent mpound of a series of thermoplastic in polymers and copolymers which widely used for containers, wrapping a, electrical insulation, pipe, conduit, l a variety of other industrial and sumer products. Vinyl chloride has n made commercially in this country ce 1939, and present production is in ess of seven billion pounds per year. e vinyl chloride industry divides into ee segments: monomer production, ymer production, and fabrication. oduction of the monomer is a largele continuous process, involving only ew firms. There are comparatively few ployees in this segment of the indus; because the processes lend themves to automation.

Vinyl chloride (VC) is used primarily the production of polyvinyl chloride VC), a resin which is produced through ich processing. The conversion of the monomer into a polymer or copolymer an incomplete process, i.e., not all of monomer is reacted.

PVC is fabricated by a variety of techques, including extrusion, injection lding and calendering, to form a fined product that needs no further inical handling. The vast majority employees involved in the VC industry employed by fabrication firms. Such ms range in size from those with few ployees and simple equipment to large nts involving many employees and nsiderable capital.

Vinyl chloride (VC), a gas at ambient mperature and pressure, is a chlorited hydrocarbon, which heretofore has en regarded as having moderate liver xicity. The initial standard, contained Table G-1 of 1910.93, established a iling value of 500 parts of VC per milon parts of air.

(2) *The emergency temporary standard.* On January 22, 1974, the Occupaonal Safety and Health Administran (OSHA) was informed by the Naonal Institute for Occupational Safety id Health (NIOSH) that the B. F. oodrich Chemical Company had reorted that deaths of several of its employees from a rare liver cancer (angiosarcoma) may have been occupationally related. As a result of this notification and after consultation with NIOSH, and a joint inspection of the B. F. Goodrich plant by OSHA, NIOSH and the Kentucky Department of Labor, a fact-finding hearing was announced on January 30, 1974 (39 FR 3874) and held on February 15, 1974.

Information obtained from this hearing, particularly the preliminary reports of experiments conducted by Professor Cesare Maltoni of the Instituto di Oncologia, Bologna, Italy, demonstrated that vinyl chloride induced angiosarcoma in rats at levels as low as 250 ppm, and in other species at higher levels. Experiments performed at lower levels of exposure were not completed at that time. Other testimony from medical witnesses and NIOSH, and the results of autopsies, led to the conclusion that the Goodrich workers had angiosarcoma of the liver and that VC probably was the causal agent in the angiosarcomas observed.

In post hearing comments, additional angiosarcoma deaths were reported among workers who had been exposed to VC in plants operated by Union Carbide Corporation, Firestone Plastics Corporation and Goodyear Tire & Rubber Company.

On the basis of all information available at that time, and the fact that employees were being exposed at levels around the experimentally observed effect level of 250 ppm, an emergency temporary standard (ETS) was promulgated on April 5, 1974 (39 FR 12342) pursuant to section 6(c) of the Act, as 29 CFR 1910.93q.

This standard reduced the permissible exposure level from a ceiling of 500 ppm to a 50 ppm ceiling, and established other requirements, including, for example, monitoring and respiratory protection. It was expressly recognized that this standard limiting exposures to a 50 ppm ceiling was a tentative, interim standard, and that the whole question of exposure to VC would be considered more fully in the light of additional information, especially the results of experiments which were known to be underway at that time.

On April 15, 1974, information and data were presented to representatives of OSHA, NIOSH, and the Environmental Protection Agency by the Industrial Bio-Test Laboratories, Northbrook, Illinois, concerning results of animal exposure studies with VC. These studies were sponsored by the Manufacturing Chemists Association. Although only preliminary in nature at that time, these results revealed that 2 out of 200 mice exposed to VC concentrations of 50 ppm for 7 hours a day, five days a week, for approximately 7 months, had developed angiosarcoma of the liver.

(3) *The proposed permanent standard.* Based on the demonstrated evidence of VC's carcinogenicity in three animal species (rats, mice and hamsters), and the substantial probability that VC had been the causal agent in the cases of liver angiosarcoma found in workers both here and abroad, OSHA proposed to revise 1910.93q and published a comprehensive proposal (39 FR 16896) on May 10, 1974, to protect employees from hazards of exposure to VC. The proposal called for limitation of employee exposure to VC to "no detectable level," as measured by a sampling and analytical method sensitive to 1 ppm, with an accuracy of 1 ppm ±50 percent. The proposal also called for the establishment of regulated areas and limited access to such areas to authorized persons. A requirement for monitoring of employee exposures was proposed, along with engineering and work practice controls to be implemented when exposures over the detectable limit were measured.

Respiratory protection would have been required while engineering and work practice controls were being implemented or where exposures exceeded the permissible limit even after feasible engineering controls were instituted.

In addition, the proposed standard included requirements for medical surveillance, protective clothing, emergency procedures, training, specific protection during maintenance and decontamination operations, transportation loading and unloading operations and recordkeeping.

(4) *Hearing on the proposal.* The proposal, as published on May 10, 1974, allowed 30 days for interested parties to submit written comments and to request an informal rulemaking hearing. Informal contacts with OSHA staff and early responses indicated that the subject was of great interest and importance to many persons. Because of the limited time available before expiration of the six month period provided in section 6(c)(3) of the Act for promulgation of a final standard, it was decided to hold a hearing as soon as possible. Accordingly, on May 24, 1974, a notice of a hearing was published (39 FR 18303), setting a hearing date of June 25, 1974. The hearing was conducted from June 25 through June 28, and again from July 8, through July 11, before Administrative Law Judge Gordon J. Myatt. All participants were given the opportunity to present testimony and to cross-examine other witnesses. Persons participating in the hearing were given until August 23, 1974, to file additional posthearing comments, including various items of information which were requested during the examination of witnesses.

(5) *Economic and technical impact study.* During the hearing, OSHA determined that additional facts would be needed to determine the practicality of certain aspects of the proposed standard. Accordingly, OSHA contracted an independent consultant, Foster D. Snell Corporation, to conduct studies of the feasibility of compliance at various exposure levels, including those proposed by OSHA and others advanced by industry spokesmen. Snell was also commissioned to collect information regarding the economic costs of compliance. This action was announced at the close of the hearing, and Judge Myatt further announced that the record would be kept

pen for a period of time beyond August 9, to allow interested persons to comment in writing on the study. On August 8, 1974, OSHA announced that the preliminary study was available and that comments were to be submitted no later than September 6, 1974 (39 FR 30844). On September 13, 1974, OSHA invited comments on both the preliminary and the final study, which was to be received on or before September 25, 1974 (39 FR 33009).

(6) *Environmental impact statements.* A notice of intent to file an environmental impact statement assessing the impact of a proposed standard on occupational exposure to VC was published in the FEDERAL REGISTER on April 24, 1974 (39 FR 14522). The notice invited any person having information or data on the environmental impact to submit it to OSHA by May 17, 1974. On June 12, 1974, a draft environmental impact statement was prepared and circulated to all interested persons. Ten copies were forwarded to the Council of Environmental Quality (CEQ), which published notice of its filing and availability in the FEDERAL REGISTER on June 25, 1974 (39 FR 22975). A 45 day period was allowed for the submission of comments on the draft statement. On September 5, 1974, the final environmental impact statement was prepared and a copy of it and all substantive comments were sent to appropriate governmental agencies, private organizations, and other interested persons. CEQ published a notice of availability for the final statement on September 6, 1974 (39 FR 32350). The submission of comment was invited until September 25, 1974. The final statement and all significant comments have been carefully considered in arriving at the final standard on occupational exposure to VC.

(7) *The record.* The record in this proceeding is one of the most extensive ever relied upon by OSHA. It consists of pre- and post-hearing comments and testimony received at both factfinding and rulemaking hearings, the studies and inspections conducted by OSHA personnel, the environmental impact statements, the economic and technical impact studies, and all other relevant information. In all, over 600 written comments have been received, with more than 200 separate oral and written submissions made with regard to the two hearings. The record itself exceeds 4,000 pages. Employers, employees, labor unions, public health groups, independent experts, physicians, research scientists, and specialists in many fields have been invited to submit information and have made their views, knowledge and experience available to OSHA. The entire record encompassing these submissions was thoroughly reviewed and evaluated in reaching the determinations set forth below.

II. *Findings regarding carcinogenicity, exposure levels and feasibility*—(1) *Carcinogenicity of vinyl chloride.* The carcinogenicity of vinyl chloride for three animal species (rat, mouse, hamster) has been documented on the record by the studies of Maltoni and Bio-Test Laboratories. Moreover, Maltoni's investigations have demonstrated a dose-dependent relationship for induction of tumors (i.e., more tumors occur at higher exposure levels), including angiosarcoma of the liver, in rats. The investigations of Industrial Bio-Test Laboratories have demonstrated a similar relationship for both rats and mice. These investigators have induced angiosarcoma of the liver in rats and mice at exposure concentrations of 50 ppm, and in hamsters at higher concentrations of exposure. Additional tumors involving other organs, including the kidneys, lungs, and skin of exposed animals, were also observed in frequencies much in excess of control animals. The incidence of tumors in mice in the Industrial Bio-Test Laboratories investigations is particularly pertinent. Of 200 mice (100 males, 100 females) exposed to 50 ppm of vinyl chloride by inhalation for eleven months, 103 died. Sixty-four animals died without gross postmortem pathologic examination being performed. Of the 36 remaining animals for which a gross postmortem pathologic examination was performed, 13 (36 percent) were found with liver tumors (including angiosarcomas), 21 (58 percent) with lung tumors, 9 (25 percent) with skin tumors, and one with a kidney tumor.

According to the 1970 report by the Surgeon General's Ad-Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens, the finding of cancer in two or more animal species may be extrapolated to indicate a carcinogenic hazard to humans. Here, such a finding was made in three species that were exposed to VC by inhalation—a route comparable to employee exposure. In addition, there were at least 13 confirmed cases of angiosarcoma of the liver among employees exposed to VC, a particularly significant number in view of the extreme rarity of this cancer in the U.S. adult male population (testimony of Dr. Marcus Key, Director of NIOSH, at the rulemaking hearing).

The findings of angiosarcoma of the liver in both experimental animals and exposed employees is compelling evidence that exposure of humans to vinyl chloride induces this tumor. Industry spokesmen, at the hearing, conceded that VC is carcinogenic for humans (e.g. testimony of Dr. McBurney, Rulemaking hearing, 1041). Accordingly, it is concluded that VC must be regarded as a human carcinogen, and the probable causal agent of angiosarcoma of the liver, and that exposure of employees to VC must be controlled.

Additional evidence of tumor induction in a variety of other organs, including lung, kidney, brain and skin, as well as non-malignant alterations, such as fibrosis and connective tissue deterioration, indicates additional oncogenic and toxicologic properties of vinyl chloride, which must be considered in establishing control regulations. (See testimony and results of studies by Bio-Test Laboratories, Tabershaw-Cooper, Maltoni, NIOSH, and Selikoff.)

(2) *Exposure limits.* Upon finding that exposure of employees to vinyl chloride may create a carcinogenic hazard, the amount of exposure which is hazardous must be determined. The Surgeon General's Ad Hoc Committee referred to above concluded that safe exposure levels for carcinogenic substances cannot be scientifically determined. This position is supported by the testimony of NIOSH at the hearing, its recommendations for a standard of no detectable level, and by the testimony of expert witnesses from the National Cancer Institute.

Several witnesses and persons who submitted comments have taken a contrary view and have suggested that man is less sensitive to biologic aberrations induced by vinyl chloride exposure than experimental animals. Proponents of this position have argued that if humans were as sensitive as rodents, an "epidemic" of cancer resulting from VC exposures should have already been discovered among employees. They also argue that the employees in whom tumors have been observed are those who have considerable employment experience as polymerization reactor cleaners. Because it is generally agreed that reactor cleaning involved high exposures to vinyl chloride in years past, it is argued that the lower levels currently found in the workplace have not induced cancer and are therefore safe. We reject this argument.

The fact that approximately three-quarters of those employees with the longest exposure to VC (greater than 20 years since initial exposure) have not yet been located, makes it impossible to determine the actual number of affected employees. The cases of liver tumors observed to date have an average latency period, since initial exposure, of approximately 20 years. If it is assumed that induction of angiosarcoma is a dose-related phenomenon, and if employees engaged in cleaning reactors did, in fact, receive larger doses of vinyl chloride, it would be expected that such tumors would be observed earlier for this employee population. For this reason, the significance of presumed lower doses cannot be accurately assessed until a longer period of time has passed, as a longer induction period would be expected.

Initiation of exposure to chemical carcinogens and induction of cancer are not necessarily synchronous events. Because of the physiologic complexities involved with carcinogenesis, induction of tumors does not occur in all employees with similar exposure histories. For example, Dr. Schneiderman of the National Cancer Institute emphasized during his testimony that only about a fifth of longer-term heavy smokers develop lung cancer. Accordingly, the industry contention that exposure levels have been dramatically reduced since the 1940's is not reliable evidence that current levels of exposure are safe.

Some industry spokesmen also suggested that the apparent nonrandom distribution of observed cancer in employees may indicate an exposure threshold for tumor induction, based on variations in the workplace design or practice and resultant employee exposures

(testimony and questioning by Tenneco Chemicals, Inc.). It has also been emphasized that in only 3 of 6 polymerization plants where employees have been exposed to VC for more than 20 years have any employees developed angiosarcoma of the liver. This argument is very similar to that raised concerning variability of past employee exposure. Although geographic and workpractice differences may ultimately be demonstrated to be factors in distribution of angiosarcoma, sufficient information is unavailable to exclude from consideration of risk those employees in workplaces for which cases of angiosarcoma have not been observed.

It has also been suggested that the absence of cancer in a population of 335 Dow Chemical Company polymerization employees monitored over a period of 7 years, indicates that exposure to vinyl chloride at concentrations of less than 200 ppm is safe. (See study by Dr. Cook, submitted at the hearing by Dow Chemical Company.) However, the group surveyed did not include all workers who had been exposed, and the missing employees included many who had the longer term (over 20 years) exposures. Moreover, the statistically insignificant size of the sample population decreases the possibility that tumors would be observed.

Dow also presented preliminary data in testimony at the hearing on the possible metabolic pathways of VC. The hypothesis presented was that VC may exert its carcinogenic effect by a metabolite, and that the metabolite is produced only when VC is metabolized by a secondary metabolic pathway operating only when enzymes regulating the primary pathway are saturated, as would be the result at higher exposures. The preliminary data indicated the possibility of an additional pathway for metabolism of VC in rats exposed to concentrations of VC in excess of 220 ppm. However, the occurrence of angiosarcoma in both rats and mice at VC exposure concentrations of 50 ppm indicates that if a metabolite of VC is the ultimate carcinogen, then it must be generated at lower exposure concentrations in these species. Although this research may be helpful to the thorough understanding of the carcinogenicity of VC, it appears that it does not yet offer evidence which can assist in determination of safe exposure concentrations for employees, or even that such safe exposures exist.

A number of witnesses representing employers have stressed that there is no evidence of cancer, either in employees or experimental animals, at exposure concentrations of VC less than 50 ppm. (See e.g., testimony of Firestone, Tenneco Chemicals.) The conclusion of these witnesses was that no decision can be made concerning risk of exposure to VC at concentrations less than 50 ppm.

On the other hand, the testimony of most expert witnesses, including some industry biomedical experts, stated that quantification of a safe exposure concentration is not possible with the present state of scientific knowledge. (See e.g., testimony of Selikoff, Firestone, NCI, and NIOSH.)

In our view, the demonstration of cancer induction in humans at a particular level is not a prerequisite to a determination that a substance represents a cancer hazard for humans at that level. It would be imprudent to assume man to be less sensitive to VC exposure than experimental animals in the absence of conclusive evidence. It would also be unfounded to assume that animals will not develop tumors when exposed at concentrations of VC of less than 50 ppm. Should a sufficiently large number of experimental animals be exposed to VC at concentrations of less than 50 ppm, Schneiderman said that it would be expected that some would develop VC induced tumors.

(3) *Feasibility.* There is virtually no dispute that most, if not all, fabricators are currently capable of reaching exposure levels of 1 ppm through engineering controls. These employers employ well over 95 percent of all employees exposed to VC. Indeed, several fabricators are already operating at this level (see SPI testimony). However, industry spokesmen have universally claimed that it is infeasible for the VC and the PVC industries to remain below 1 ppm consistently, using engineering controls. In addition, the Snell study on technical feasibility concluded that a 1 ppm ceiling is not feasible for the VC and PVC industries with present technology, but that the VC industry could currently attain lower exposure levels than the PVC industry. Labor union spokesmen and the Health Research Group, Inc., however, have suggested that such a level is attainable.

Since there is no actual evidence that any of the VC or PVC manufacturers have already attained a 1 ppm level or in fact instituted all available engineering and work practice controls, any estimate as to the lowest feasible level attainable must necessarily involve subjective judgment. Likewise, the projections of industry, labor, and others concerning feasibility are essentially conjectural. Indeed, as Firestone has suggested, it is not possible to accurately predict the degree of improvement to be obtained from engineering changes until such changes are actually implemented.

We agree that the PVC and VC establishments will not be able to attain a 1 ppm TWA level for all job classifications in the near future. We do believe, however, that they will, in time, be able to attain levels of 1 ppm TWA for most job classifications most of the time. It is apparent that reaching such levels may require some new technology and work practices. It may also be necessary to utilize technology presently used in other industries. In any event, the VC and PVC industries have already made great strides in reducing exposure levels. (See testimony of Dow Chemical Co., TR 973). For example, B. F. Goodrich testified (TR 1120) that it has reduced average exposure levels in several PVC plants from 35-40 ppm early this year to 12-13 ppm at the time of the hearing. We are confident that industry will continue to do so.

(4) *Conclusions.* The conclusions below are based on a thorough review and evaluation of all the evidence submitted. Where decisions can be based on record evidence, this has been done. Where, however, factual certainties are lacking or where the facts alone do not provide an answer, policy judgments have been made.

There is little dispute that VC is carcinogenic to man and we so conclude. However, the precise level of exposure which poses a hazard and the question of whether a "safe" exposure level exists, cannot be definitively answered on the record. Nor is it clear to what extent exposures can be feasibly reduced. We cannot wait until indisputable answers to these questions are available, because lives of employees are at stake. Therefore, we have had to exercise our best judgment on the basis of the best available evidence. These judgments have required a balancing process, in which the overriding consideration has been the protection of employees, even those who may have regular exposures to VC throughout their working lives.

Based on the available evidence and in view of the above considerations, including feasibility, we believe that employee exposures to VC must be reduced to a 1 ppm time-weighted average (TWA). We also believe that PVC and VC establishments will, in time, be able to attain that level through engineering controls, and that fabricators can do so in the immediate future.

In addition to the TWA requirement, we have established a 5 ppm ceiling (averaged over a 15-minute period) in order to prevent exposure of employees to unacceptable high excursions. From an operation standpoint, this ceiling level is realistic because minor excursions up to the ceiling level are likely to occur on a regular basis.

III. *The final standard.*—(1) *Scope and application.* Both the ETS and the proposal would apply the standard to the entire VC industry, including manufacturers of VC and PVC and fabricators, but excluding employers handling or using fabricated products made from VC.

There is no dispute that a standard is required for the monomer and polymer industries. However, the Society of Plastics Industry (SPI) and various fabricators (see testimony of Goodyear, General Cable, etc.) recommended that fabricators be excluded from the standard, or that a separate requirement be established for them because many of them were already at or below the proposed ceiling level.

The record evidence establishes that at least some employees in the fabricating industry are exposed in excess of the permissible control limits (See NIOSH testimony, TR 106; Robintech TR 642). In these circumstances, we believe that it is imprudent to grant a blanket exemption for all fabricators. Therefore, the final standard is applicable to the fabrication industry, as well as the monomer

and polymer industries. Employers who, in fact, are substantially below the exposure limit will be subjected to only minimal burdens by virtue of the "action level" to be discussed below.

Where employers in the fabricating industry have exposures approaching the permissible limit, they will appropriately be subject to the standard. Employers handling or using fabricated products made of PVC were not included in the ETS or the proposal and are excluded from the final standard. This conclusion is based on the absence of adequate evidence of exposure to VC in these operations. The final standard clarifies the exemption by defining a fabricated product as a product made wholly or partly from PVC which does not require further processing at temperatures, and for times, sufficient to cause mass melting of the PVC. SPI and others (cf. TR. 344) requested that PVC resins with less than 0.1 percent residual monomer be exempted from the regulation now, and that the exemption level be reduced to 0.01 percent in three years. SPI suggested that the exemption of materials with less than 0.1 percent of 14 carcinogens from 29 CFR 1910.93p (39 FR 3756) was an appropriate precedent. The cases are not comparable, because no attempt had been made to set air concentration limits for the 14 carcinogens. The record did not include information that reliable monitoring and measuring techniques were available. Moreover, the exemption did not exempt airborne traces of carcinogens. The administrative cutoff was provided to avoid regulation of materials about which there was no health hazard information, and which would have broadly extended the application of the regulation beyond the record. Herein, no information was presented to show safe concentration results from the use of resins with specific levels. Indeed, the proposal to change the level later, when improved technology would permit such reduction, would seem to indicate that SPI has doubts about the safety of 0.1 percent residue level. Diamond Shamrock (Exhibit 142) testified that there is no direct relation. They indicate that the airborne concentration is more related to the physical form of the resin and the ventilation provided. Also, monitoring data from industry (cf. Exhibits 131, 168, 170) and OSHA (Exhibit 151) indicate that levels in excess of 1 ppm may be found in fabrication operations. In view of these facts and of the opportunity for employers to discontinue many duties upon a showing of no exposures above the action level, it does not appear that any residue exemption is either justified or necessary at this time. This course also agrees with a number of industry proposals (cf. TR 669).

SPI (TR 345), among others, asked that compounded PVC pellets be exempted from the standard on the grounds that the pellets had too low a residue to cause harmful or measurable emissions. While it appears that PVC pellets would have a lower residue level than virgin PVC, the fact that the pellets must be heated to a molten mass at the same temperature as PVC, for further processing, indicates that a potential for release of the residue still exists. It appears that the exemption of fabricated products should be limited to just those items which will not undergo such mass heating. Further, the opportunity to demonstrate that exposures are below the action level, and thus, discontinue many duties of the standard, provides a more positive control and an adequate relief.

(2) *Permissible exposure limit.* The standard sets an exposure limit of 1 ppm averaged over any 8 hour period, and a ceiling of 5 ppm averaged over any period not exceeding 15 minutes.

As more fully discussed above, this limit is based on an evaluation of the best available evidence and on a judgment that the health and safety of employees must be protected to the fullest extent feasible. In view of the fact that release of VC in the VC and PVC manufacturing processes are variable, the 1 ppm ceiling level provided in the proposal would require maintenance of an average level significantly more difficult to attain through feasible engineering controls. Therefore, the exposure limit prescribed in the proposal has been rejected.

(3) *Action level.* The final standard, unlike the ETS and the proposal, provides for an "action level" of 0.5 ppm TWA, one-half of the permissible exposure limit. The purpose of the action level is to minimize the impact of the standard on the employers who have attained exposure levels well below the permissible limit. Thus, where the results of monitoring under paragraphs (d)(1) or (d)(2) demonstrate that no employee is exposed in excess of 0.5 ppm TWA, employers may, in effect, be exempted from some provisions of the standard. For example, fabricators who are below the action level are not required to provide medical surveillance or to monitor again, unless the employer has reason to suspect that any employee is exposed in excess of the action level. In our judgment, exposures below the action level do not present a sufficient hazard to warrant application of the entire standard to the many employers who are or will be below that level.

(4) *Monitoring.* The final standard, like the proposal, requires that individual employee exposure levels be determined. This may be accomplished by personal or area monitoring. Some witnesses and persons who submitted comments did not understand the meaning of the term "95 percent confidence level" in the proposal. Essentially it means that the employer is required to take a sufficient number of measurements so that the results obtained are statistically valid. We have modified the proposal to establish accuracy range requirements for various measurement levels. These ranges are narrow enough to ensure that a determination of compliance can be made, and broad enough to allow the application of a variety of technologies.

All covered employers are required to conduct initial monitoring. Where monitoring and measuring results are at or below the action level, no further monitoring is required unless the employer has reason to suspect that any employee is exposed in excess of the action level, or unless changes have been made in production, process, control, type of resin, etc.

Where the exposure level, without regard to respirators, exceeds the permissible levels, monitoring must be conducted at least monthly. Where exposures are less than the permissible levels, but greater than the action level, monitoring must occur at least quarterly.

(5) *Methods of compliance.* The standard, like the proposal, requires that employers immediately institute feasible engineering and work practice controls to reduce exposures to at or below the permissible exposure limit.

Where feasible engineering and work practice controls will reduce exposures below the permissible levels, they must be instituted. Where such controls will not reduce exposures below the permissible level, they must nonetheless be implemented to reduce exposures to the lowest practicable level, and be supplemented by the use of respirators to provide the necessary protection. Thereupon, a continuing program of engineering and work practice controls must be instituted to reduce exposures to the lowest practicable level. When exposures are at or below the permissible exposure limits, the program may be discontinued.

In addition, a plan for achieving control by engineering and work practice methods must be drawn up and be made available, upon request, to representatives of OSHA and NIOSH.

We recognize that many employers covered by the standard can not currently achieve compliance with the permissible exposure limit solely by the use of feasible engineering and work practice controls. The record also reflects broad generic distinctions between the compliance capabilities of the VC and PVC industries. Some industry spokesmen, including SPI (TR. 358–362), recommended that a schedule of different permissible exposure limits and compliance dates be established for the VC and PVC segments of the industry.

This view assumes that the ability and the time required to feasibly reach increasingly lower control levels is similar within each industry, but differs markedly between industries. While the record does suggest that such differences do exist between industries, as noted above, it is clear that intra-industry differences also exist. Thus, the ability and time required by each employer to attain lower control levels may depend upon such factors as the climate in which the plant is located, the age of equipment, the size of reactors, or the type of resin manufactured or used. (Snell study, Firestone testimony, etc.)

Monitoring data also tends to support such intra-industry variations. (See, e.g. Dow, Firestone, Tenneco.)

As noted above, the standard requires all employers to institute feasible engineering controls to the fullest extent and to continue to improve and apply engi-

neering controls until full compliance is achieved.

We have not established any deadlines for full compliance through engineering controls because we are presently unable to determine when it will be feasible for most establishments to reduce exposure levels to the permissible level.

We also believe that the requirement that each employer reduce airborne concentrations to the permissible level, or to the lowest level feasible as soon as practicable will provide for inter-industry and intra-industry technological differences which do exist, and will avoid the setting of separate industry standards on the basis of the general situation and conditions in each industry.

(6) *Regulated areas.* The proposed standard would have required that regulated areas be established, that access be limited to authorized employees, and that daily rosters or summaries of those entering be kept for at least 20 years. In objection to these requirements, it was asserted that such control of access was not necessary from a health standpoint. Secondly, it was claimed that these controls would interfere with operations by preventing access of needed employees or non-employees, such as contractors, truck drivers, customers and consultants.

The purpose of establishing regulated areas in the proposal was to limit the risk of exposure to as few employees as possible. This concern is still paramount, and thus the limited access feature remains. The final standard amends the proposal slightly to allow "authorized persons" to enter regulated areas. This change, it is felt, will allow operations to continue without undue interference. The final standard has also increased the length of time daily rosters must be maintained from 20 to 30 years. This change was based largely on epidemiological considerations. (See NIOSH testimony, tr. 119.)

(7) *Respiratory protection.* The final standard, like the proposal, requires the use of respirators where employee exposures exceed the permissible control level. Industry representatives made a number of objections to proposed requirements for respiratory protection. They stated that the "no detectable level" would effectively require continuous wearing of respirators in PVC and VC plants, and that this is not feasible because respirators are cumbersome, present a safety hazard, and employees would not use them.

We would agree that respirators have many drawbacks; the proposal did not contemplate them as a final solution. The record shows that the PVC industry particularly may need several years before plant environmental levels can be reduced so that respirators are necessary only occassionally. However, we cannot agree that respiratory protection should not be required simply because it is inconvenient, may require additional personnel, interferes with production, or may require extensive retraining of employees and restructuring of work practices. We have carefully considered all the objections, and have concluded that if the environmental level is not controlled to the permissible exposure limit, then employees must be afforded respiratory protection.

While exposures in excess of the permissible level do constitute a hazard, we believe that it is necessary to mitigate some of the problems associated with implementing a program of respiratory protection while employees are being fitted and trained in respirator use, and while other adjustments which may be required are implemented. Therefore, until January 1, 1976, where exposures are not in excess of a 25 ppm ceiling, each employer must provide each employee with an appropriate respirator. However, employees whose exposures do not exceed a 25 ppm ceiling, may decline to use the respirator, in which case the employer is not obligated to require its use. During this adjustment period, employees will be trained in the uses, purposes and limitations of respirators, and the hazards of exposure to vinyl chloride. Moreover, each employee will be notified in writing if he has been exposed in excess of the permissible exposure limit.

Where exposures exceed a 25 ppm ceiling, respiratory protection is mandatory in light of our judgment that much greater risks are associated with such exposures.

The provisions in the final standard regarding the selection and use of respiratory protective devices differ from those in the proposal. The descriptions of atmosphere-supplying respirators have been revised to indicate more clearly the types of devices intended, and the maximum permissible concentration level for each device. Moreover, the number of types of atmosphere-supplying devices has been increased.

At the hearing Mr. Edwin C. Hyatt, an OSHA consultant, made suggestions regarding the use of particular respiratory devices. We have concluded that his suggestions are meritorious. Therefore, the provisions for selection of atmosphere-supplying devices follow closely the recommendations contained in his testimony of SPI and B. F. Goodrich) (TR with Hyatt's suggestions. (See e.g. testimony of SPI and B. F. Goodrich) (TR 85 ff). We had originally omitted air-purifying respirators because none had been approved by NIOSH for use against VC, principally because they lacked indicators to signal the expiration of the service life of the sorbent. Hyatt and other witnesses discussed in detail the desirability of being able to use canisters or cartridge air-purifying respirators, provided a sorbent could be shown to effectively absorb vinyl chloride with an adequate service life. Recently, OSHA has received respiratory data from laboratories regarding the effectiveness of commercially available canisters and cartridges for vinyl chloride. These evaluations were conducted separately by NIOSH and by the B. F. Goodrich Company and submitted to OSHA in post-hearing comments. The results indicate that certain presently available canisters and cartridges effectively absorb vinyl chloride at relatively low concentrations. In discussions of these findings with NIOSH, it has indicated that it is willing to consider on an expedited basis the approval of air-purifying respirators for use against VC. Consequently, we have included three types of air-purifying respirators in the list of acceptable units, subject to the approval of such units by NIOSH. The maximum concentration for which each respirator may be used is based upon our evaluation of the data submitted by NIOSH and Goodrich. Because air-purifying respirators do not indicate sorbent exhaustion or breakthrough of VC, and because VC has no inherent warning properties at levels for which these devices are used, strict administrative controls will be required for their use. Such controls include a program to assure timely replacement of canisters or cartridges and an alarm system to alert employees when vinyl chloride concentrations exceed the concentrations allowed for the particular type of respirator in use.

(8) *Hazardous operations.* This is a new section within the final standard. It encompasses essentially the proposal's requirements for maintenance and decontamination but has restated them in terms of performance language to allow greater flexibility for employers to deal with such operations. The intent of the new section is to protect employees engaged in activities that present a risk of exposure to vinyl chloride in excess of the permissible levels. An example would be the cleaning of a filter where resin containing high residual monomer is trapped.

The proposal's requirement for full-body, impervious clothing has been replaced by the direction to use impervious garments suited to the particular situation and probable extent of exposure. Thus, full-body clothing is not always necessary, and is therefore not required where less protection is adequate. Since vessel entry falls within the definition of a hazardous operation, the vessel entry section of the proposal has been deleted from the final standard.

(9) *Emergency situations.* The definition of emergency has been recast in terms of an unexpected massive release. The main objection to the section on emergency situations in the proposal was that, as the term was defined, many ordinary leaks or operations resulting in a small release of vinyl chloride would be considered emergencies. This was not the intent of the proposal. The final standard has been clarified to correct this ambiguity. It should be noted that the written operational plan required by the standard need not be developed for minor excursions above the permissible exposure limit, and that such excursions need not be reported.

(10) *Signs and labels.* The thrust of the signs and labels section is to apprise employees of the cancer and fire hazards. No objections have been raised with respect to informing employees of the fire hazard. However, a number of objections were raised at the hearing and in written submissions to the requirement that the word "cancer" appear on all signs and labels. The principal argu-

ent advanced against its use was that he term "cancer" or "cancer-suspect gent" scares employees and that instead, the message should contain instructions on how to deal with the substance (TR. 347). We believe that a luted form of warning will not suffice. Ve appreciate the concern of employers ith the reaction of their employees. But e consider it imperative that a worker e fully informed, and that he realize the ossible risks involved in his occupation. oupled with the training requirement the standard, we believe that the signs nd labels required will adequately inrm employees of the hazard. In addion, such signs will warn unauthorized ersonnel to keep out of regulated areas.

The proper application of most protecive measures requires an amount of raining and indoctrination of employees hat cannot easily be conveyed on a sign r label. Also, the variety of measures hat could be prescribed would result in n unwieldly or excessively detailed legnd. Consequently, the required message n signs and labels will not include inormation on precautions, relevant ymptoms, etc. The addition of suitable nformation by the employer would be ermitted, providing it does not detract n any way from the required statement.

The requirement in the proposal for abeling containers of vinyl chloride has een amended by deleting the reference o the possible hazard of violent polymrization. Very little information was eveloped on this hazard during the tandard-setting procedure. It does apear that this hazard is essentially under ontrol and that the fire and carcinoenic hazards at present are the most ignificant. Since labeling or placarding hat is in compliance with the U.S. Deartment of Transportation regulations 49 CFR Part 173, Subpart H) already arns of the fire hazard, only a statenent concerning the carcinogenic hazrd need be added to the Department of ransportation labels.

(11) *Medical surveillance.* The principal questions that have been raised regarding medical surveillance are the ecessity and efficacy of requiring cerain specific serum enzyme determinaions (SGOT-12 series) and the applicaion of medical examination requirenents to the fabrication segments of the ndustry where employees are exposed to ower levels of VC. The objection has also een raised that the specification of tests nd procedures interferes with the application of advances in medical knowlidge.

A particular difficulty in considering nedical surveillance is that the most ommonly discussed lesion, angiosarcoma of the liver, currently cannot be iagnosed until the victim is terminal nd, usually, within months of death. Precursor physiologic alterations, which night be reversible, have not yet been irectly associated with the lesion. Consequently, there are no specific diagnoic tests which can be prescribed which will determine presence or absence of his tumor at an early stage of development. However, most medical witnesses indicated that the medical tests proposed are currently the only ones available which are useful for medical surveillance (TR 121, Exh. 95, TR 589-591). Consequently, the specific blood tests proposed have been retained as a minimum requirement to assist the examining physician in determining fitness of potential employees for assignment to workplaces involving VC exposure. In addition, alternative medical examinations may be used where the examining physician determines that they are at least as good as those specified by the standard.

The Tabershaw-Cooper study and the various animal experiments suggest that VC may produce a wide spectrum of malignant and non-malignant disorders. The general scope of the required medical examination has, therefore, been broadened to include kidneys, skin, connective tissue, spleen, and pulmonary system, as well as the liver. No additional specific procedures or tests are required, but recommendations have been included in the Appendix to assist the examining physician. Because of the nonspecific nature of the required medical tests, it is not appropriate to prescribe timing, or type of followup tests, or to mandate withdrawal from exposure based solely on results of the tests. Instead, the employer is required to obtain a statement from the examining physician of the employee's suitability for continued exposure, when the examining physician has completed such tests as he considers appropriate. The employer is required to withdraw an employee only when this statement indicates that the employee may be at added risk from continued VC exposure.

As with monitoring, there appears to be no basis for complete exemption of the fabrication industry from the requirement for medical examination. The record does show fabricating establishments with concentrations of VC monitored considerably above the action level. In these instances, medical surveillance of affected employees will provide baseline data for future evaluation of their health, even if both monitoring and medical surveillance are discontinued because improved controls reduce concentrations below the action level. Where exposures are below the action level, the medical surveillance requirements do not generally apply.

(12) *Training.* A separate provision for employee training has been added to the final standard rather than including it within the section on emergency situations as in the proposal. The new paragraph provides for training of employees concerning the carcinogenic hazard of VC, emergency procedures, the need for monitoring and an annual review of the standard. It also provides for training of employees concerning the purpose for, proper use of, and limitations connected with respiratory protection.

(13) *Records and reports.* The provisions for recordkeeping contained in the final standard require the preparation and maintenance of essentially the same information required by the proposal. The major change from the original proposal is the requirement for maintenance of monitoring records and daily roster sheets of authorized persons for 30 years, instead of 20 years. Additionally, the employer is required to maintain medical records for the duration of an employee's employment plus 20 years, or 30 years, whichever is longer. The original proposal called for only 20 years.

This change has been implemented because the latency period for induction of angiosarcoma ranges up to 30 years from initial exposure. Therefore, as a minimum, medical records must be maintained for at least that long. It should be noted that spokesmen for both labor and industry recommended that this change be made.

The reporting requirements are not significantly different from those in the original proposal. However, instead of the requirement for reporting incidents which result in the release of VC into areas where employees may be exposed, the final standard clarifies our original intent by stating that only emergencies must be reported. Also the requirement for filing a detailed, written report within 15 days has been deleted. It has been concluded that submission, within 24 hours, of an initial report that includes facts immediately available, would ordinarily be sufficient. However, if the OSHA Area Director requests further information relevant to the emergency, the employer will be required to furnish such information.

(14) *Deleted portions of the proposal.* The proposal contained provisions requiring that shower facilities and change rooms be provided, and that storage or consumption of food be prohibited in regulated areas. We have deleted these provisions because it is our conclusion they are no longer necessary. Showering facilities are not required because protective clothing, where required by the final standard, should protect employees from skin absorption by direct contact with VC and because there is no reliable evidence that VC vapor is absorbed through the skin. In addition, since we anticipate that most employees will not be wearing protective clothing and that employees who wear protective clothing will change such clothing infrequently, we are not requiring that change rooms be provided.

In addition, we feel that there is inadequate evidence showing that hazardous amounts of VC can be absorbed through ingestion. For this reason, the requirement prohibiting the storage or consumption of food in regulated areas has been deleted.

The proposal also contained provisions on maintentance and decontamination, transportation loading and unloading, and polymer handling operations. These requirements are not mentioned in the final standard because attention to these items is implicit in the requirement that each employer reach the permissable exposure limit or attain the lowest feasible level.

(15) *Effective date.* In order to ensure that affected employers and employees will be informed of the existence of these

provisions and that employers affected are given an opportunity to familiarize themselves and their employees with the existence of the new requirements, the effective date of the amendment to § 1910.93q will be January 1, 1975. To provide continued protection for employees until that date, the provisions currently contained in § 1910.93q are hereby promulgated, pursuant to section 6(b), 6(c) and 8(c) of the Occupational Safety and Health Act, as an occupational safety and health standard effective October 4, 1974. the amendment to § 1910.93q set out below will supersede these provisions as of January 1, 1975.

Accordingly, upon consideration of the whole record of this proceding, Part 1910 of Title 29, Code of Federal Regulations is amended, effective January 1, 1975, by revision of § 1910.93q to read as follows:

§ 1910.93q Vinyl chloride.

(a) *Scope and application.* (1) This section includes requirements for the control of employee exposure to vinyl chloride (chloroethene), Chemical Abstracts Service Registry No. 75015.

(2) This section applies to the manufacture, reaction, packaging, repackaging, storage, handling or use of vinyl chloride or polyvinyl chloride, but does not apply to the handling or use of fabricated products made of polyvinyl chloride.

(3) This section applies to the transportation of vinyl chloride or polyvinyl chloride except to the extent that the Department of Transportation may regulate the hazards covered by this section.

(b) *Definitions.* (1) "Action level" means a concentration of vinyl chloride of 0.5 ppm averaged over an 8-hour work day.

(2) "Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or his designee.

(3) "Authorized person" means any person specifically authorized by the employer whose duties require him to enter a regulated area or any person entering such an area as a designated representative of employees for the purpose of exercising an opportunity to observe monitoring and measuring procedures.

(4) "Director" means the Director, National Institute for Occupational Safety and Health, U.S. Department of Health, Education, and Welfare, or his designee.

(5) "Emergency" means any occurrence such as, but not limited to, equipment failure, or operation of a relief device which is likely to, or does, result in massive release of vinyl chloride.

(6) "Fabricated product" means a product made wholly or partly from polyvinyl chloride, and which does not require further processing at temperatures, and for times, sufficient to cause mass melting of the polyvinyl chloride resulting in the release of vinyl chloride.

(7) "Hazardous operation" means any operation, procedure, or activity where a release of either vinyl chloride liquid or gas might be expected as a consequence of the operation or because of an accident in the operation, which would result in an employee exposure in excess of the permissible exposure limit.

(8) "OSHA Area Director" means the Director for the Occupational Safety and Health Administration Area Office having jurisdiction over the geographic area in which the employer's establishment is located.

(9) "Polyvinyl chloride" means polyvinyl chloride homopolymer or copolymer before such is converted to a fabricated product.

(10) "Vinyl chloride" means vinyl chloride monomer.

(c) *Permissible exposure limit.* (1) No employee may be exposed to vinyl chloride at concentrations greater than 1 ppm averaged over any 8-hour period, and

(2) No employee may be exposed to vinyl chloride at concentrations greater than 5 ppm averaged over any period not exceeding 15 minutes.

(3) No employee may be exposed to vinyl chloride by direct contact with liquid vinyl chloride.

(d) *Monitoring.* (1) A program of initial monitoring and measurement shall be undertaken in each establishment to determine if there is any employee exposed, without regard to the use of respirators, in excess of the action level.

(2) Where a determination conducted under paragraph (d)(1) of this section shows any employee exposures, without regard to the use of respirators, in excess of the action level, a program for determining exposures for each such employee shall be established. Such a program:

(i) Shall be repeated at least monthly where any employee is exposed, without regard to the use of respirators, in excess of the permissible exposure limit.

(ii) Shall be repeated not less than quarterly where any employee is exposed, without regard to the use of respirators, in excess of the action level.

(iii) May be discontinued for any employee only when at least two consecutive monitoring determinations, made not less than 5 working days apart, show exposures for that employee at or below the action level.

(3) Whenever there has been a production, process or control change which may result in an increase in the release of vinyl chloride, or the employer has any other reason to suspect that any employee may be exposed in excess of the action level, a determination of employee exposure under paragraph (d)(1) of this section shall be performed.

(4) The method of monitoring and measurement shall have an accuracy (with a confidence level of 95 percent) of not less than plus or minus 50 percent from 0.25 through 0.5 ppm, plus or minus 35 percent from over 0.5 ppm through 1.0 ppm, and plus or minus 25 percent over 1.0 ppm. (Methods meeting these accuracy requirements are available in the "NIOSH Manual of Analytical Methods").

(5) Employees or their designated representatives shall be afforded reasonable opportunity to observe the monitoring and measuring required by this paragraph.

(e) *Regulated area.* (1) A regulated area shall be established where:

(i) Vinyl chloride or polyvinyl chloride is manufactured, reacted, repackaged, stored, handled or used; and

(ii) Vinyl chloride concentrations are in excess of the permissible exposure limit.

(2) Access to regulated areas shall be limited to authorized persons. A daily roster shall be made of authorized persons who enter.

(f) *Methods of compliance.* Employee exposures to vinyl chloride shall be controlled to at or below the permissible exposure limit provided in paragraph (c) of this section by engineering, work practice, and personal protective controls as follows:

(1) Feasible engineering and work practice controls shall immediately be used to reduce exposures to at or below the permissible exposure limit.

(2) Wherever feasible engineering and work practice controls which can be instituted immediately are not sufficient to reduce exposures to at or below the permissible exposure limit, they shall nonetheless be used to reduce exposures to the lowest practicable level, and shall be supplemented by respiratory protection in accordance with paragraph (g) of this section. A program shall be established and implemented to reduce exposures to at or below the permissible exposure limit, or to the greatest extent feasible, solely by means of engineering and work practice controls, as soon as feasible.

(3) Written plans for such a program shall be developed and furnished upon request for examination and copying to authorized representatives of the Assistant Secretary and the Director. Such plans shall be updated at least every six months.

(g) *Respiratory protection.* Where respiratory protection is required under this section:

(1) The employer shall provide a respirator which meets the requirements of this paragraph and shall assure that the employee uses such respirator, except that until December 31, 1975, wearing of respirators shall be at the discretion of each employee for exposures not in excess of 25 ppm, measured over any 15-minute period. Until December 31, 1975, each employee who chooses not to wear an appropriate respirator shall be informed at least quarterly of the hazards of vinyl chloride and the purpose, proper use, and limitations of respiratory devices.

(2) Respirators shall be selected from among those jointly approved by the Mining Enforcement and Safety Administration, Department of the Interior, and the National Institute for Occupational Safety and Health under the provisions of 30 CFR Part 11.

(3) A respiratory protection program meeting the requirements of § 1910.134 shall be established and maintained.

(4) Selection of respirators for vinyl chloride shall be as follows:

Atmospheric concentration of vinyl chloride	*Required apparatus*
(i) Unknown, or above 3,600 ppm	Open-circuit, self-contained breathing apparatus, pressure demand type, with full facepiece.
(ii) Not over 3,600 ppm	(A) Combination type C supplied air respirator, pressure demand type, with full or half facepiece, and auxiliary self-contained air supply; or (B) Type C, supplied air respirator continuous flow type, with full or half facepiece, and auxiliary self-contained air supply.
(iii) Not over 100 ppm	(A) Combination type C supplied air respirator demand type, with full facepiece, and auxiliary self-contained air supply; or (B) Open-circuit self-contained breathing apparatus with full facepiece, in demand mode; or (C) Type C supplied air respirator, demand type, with full facepiece.
(iv) Not over 25 ppm	(A) A powered air-purifying respirator with hood, helmet, full or half facepiece, and a canister which provides a service life of at least 4 hours for concentrations of vinyl chloride up to 25 ppm, or (B) Gas mask, front- or back-mounted canister which provides a service life of at least 4 hours for concentrations of vinyl chloride up to 25 ppm.
(v) Not over 10 ppm	(A) Combination type C supplied-air respirator, demand type, with half facepiece, and auxiliary self-contained air supply; or (B) Type C supplied-air respirator, demand type, with half facepiece; or (C) Any chemical cartridge respirator with an organic vapor cartridge which provides a service life of at least 1 hour for concentrations of vinyl chloride up to 10 ppm.

(5) (i) Entry into unkown concentrations or concentrations greater than 36,000 ppm (lower explosive limit) may be made only for purposes of life rescue; and

(ii) Entry into concentrations of less than 36,000 ppm, but greater than 3,600 ppm may be made only for purposes of life rescue, firefighting, or securing equipment so as to prevent a greater hazard from release of vinyl chloride.

(6) Where air-purifying respirators are used:

(i) Air-purifying cannisters or cartridges shall be replaced prior to the expiration of their service life or the end of the shift in which they are first used, whichever occurs first, and

(ii) A continuous monitoring and alarm system shall be provided where concentrations of vinyl chloride could reasonably exceed the allowable concentrations for the devices in use. Such system shall be used to alert employees when vinyl chloride concentrations exceed the allowable concentrations for the devices in use.

(7) Apparatus prescribed for higher concentrations may be used for any lower concentration.

(h) *Hazardous operations.* (1) Employees engaged in hazardous operations, including entry of vessels to clean polyvinyl chloride residue from vessel walls, shall be provided and required to wear and use:

(i) Respiratory protection in accordance with paragraphs (c) and (g) of this section; and

(ii) Protective garments to prevent skin contact with liquid vinyl chloride or with polyvinyl chloride residue from vessel walls. The protective garments shall be selected for the operation and its possible exposure conditions.

(2) Protective garments shall be provided clean and dry for each use.

(i) *Emergency situations.* A written operational plan for emergency situations shall be developed for each facility storing, handling, or otherwise using vinyl chloride as a liquid or compressed gas. Appropriate portions of the plan shall be implemented in the event of an emergency. The plan shall specifically provide that:

(1) Employees engaged in hazardous operations or correcting situations of existing hazardous releases shall be equipped as required in paragraph (h) of this section;

(2) Other employees not so equipped shall evacuate the area and not return until conditions are controlled by the methods required in paragraph (f) of this section and the emergency is abated.

(j) *Training.* Each employee engaged in vinyl chloride or polyvinyl chloride operations shall be provided training in a program relating to the hazards of vinyl chloride and precautions for its safe use.

(1) The program shall include:

(i) The nature of the health hazard from chronic exposure to vinyl chloride including specifically the carcinogenic hazard;

(ii) The specific nature of operations which could result in exposure to vinyl chloride in excess of the permissible limit and necessary protective steps;

(iii) The purpose for, proper use, and limitations of respiratory protective devices;

(iv) The fire hazard and acute toxicity of vinyl chloride, and the necessary protective steps;

(v) The purpose for and a description of the monitoring program;

(vi) The purpose for, and a description of, the medical surveillance program;

(vii) Emergency procedures;

(viii) Specific information to aid the employee in recognition of conditions which may result in the release of vinyl chloride; and

(ix) A review of this standard at the employee's first training and indoctrination program, and annually thereafter.

(2) All materials relating to the program shall be provided upon request to the Assistant Secretary and the Director.

(k) *Medical surveillance.* A program of medical surveillance shall be instituted for each employee exposed, without regard to the use of respirators, to vinyl chloride in excess of the action level. The program shall provide each such employee with an opportunity for examinations and tests in accordance with this paragraph. All medical examinations and procedures shall be performed by or under the supervision of a licensed physician, and shall be provided without cost to the employee.

(1) At the time of initial assignment, or upon institution of medical surveillance:

(i) A general physical examination shall be performed, with specific attention to detecting enlargement of liver, spleen or kidneys, or dysfunction in these organs, and for abnormalities in skin, connective tissues and the pulmonary system (See Appendix A).

(ii) A medical history shall be taken, including the following topics:

(A) Alcohol intake;

(B) Past history of hepatitis;

(C) Work history and past exposure to potential hepatotoxic agents, including drugs and chemicals;

(D) Past history of blood transfusions; and

(E) Past history of hospitalizations.

(iii) A serum specimen shall be obtained and determinations made of:

(A) Total bilirubin;

(B) Alkaline phosphatase;

(C) Serum glutamic oxaloacetic transaminase (SGOT);

(D) Serum glutamic pyruvic transaminase (SGPT); and

(E) Gamma glutamyl transpeptidase.

(2) Examinations provided in accordance with this paragraph shall be performed at least:

(i) Every 6 months for each employee who has been employed in vinyl chloride or polyvinyl chloride manufacturing for 10 years or longer; and

(ii) Annually for all other employees.

(3) Each employee exposed to an emergency shall be afforded appropriate medical surveillance.

(4) A statement of each employee's suitability for continued exposure to vinyl chloride including use of protective equipment and respirators, shall be obtained from the examining physician promptly after any examination. A copy of the physician's statement shall be provided each employee.

(5) If any employee's health would be materially impaired by continued exposure, such employee shall be with-

drawn from possible contact with vinyl chloride.

(6) Laboratory analyses for all biological specimens included in medical examinations shall be performed in laboratories licensed under 42 CFR Part 74.

(7) If the examining physician determines that alternative medical examinations to those required by paragraph (k)(1) of this section will provide at least equal assurance of detecting medical conditions pertinent to the exposure to vinyl chloride, the employer may accept such alternative examinations as meeting the requirements of paragraph (k)(1) of this section, if the employer obtains a statement from the examining physician setting forth the alternative examinations and the rationale for substitution. This statement shall be available upon request for examination and copying to authorized representatives of the Assistant Secretary and the Director.

(l) *Signs and labels.* (1) Entrances to regulated areas shall be posted with legible signs bearing the legend:

CANCER-SUSPECT AGENT AREA AUTHORIZED PERSONNEL ONLY

(2) Areas containing hazardous operations or where an emergency currently exists, shall be posted with legible signs bearing the legend:

CANCER-SUSPECT AGENT IN THIS AREA PROTECTIVE EQUIPMENT REQUIRED AUTHORIZED PERSONNEL ONLY

(3) Containers of polyvinyl chloride resin waste from reactors or other waste contaminated with vinyl chloride shall be legibly labeled:

Contaminated with
VINYL CHLORIDE CANCER-SUSPECT AGENT

(4) Containers of polyvinyl chloride shall be legibly labeled:

POLYVINYL CHLORIDE (OR TRADE NAME)
Contains
VINYL CHLORIDE
VINYL CHLORIDE IS A CANCER-SUSPECT AGENT

(5) Containers of vinyl chloride shall be legibly labeled either:

(i)

VINYL CHLORIDE
EXTREMELY FLAMMABLE GAS UNDER PRESSURE
CANCER-SUSPECT AGENT

or (ii) In accordance with 49 CFR Part 173, Subpart H, with the additional legends:

CANCER-SUSPECT AGENT

applied near the labor or placard.

(6) No statement shall appear on or near any required sign, label or instruction which contradicts or detracts from the effect of, any required warning, information or instruction.

(m) *Records.* (1) All records maintained in accordance with this section shall include the name and social security number of each employee where relevant.

(2) Records of required monitoring and measuring, medical records, and authorized personnel rosters, shall be made and shall be available upon request for examination and copying to authorized representatives of the Assistant Secretary and the Director.

(i) Monitoring and measuring records shall:

(A) State the date of such monitoring and measuring and the concentrations determined and identify the instruments and methods used;

(B) Include any additional information necessary to determine individual employee exposures where such exposures are determined by means other than individual monitoring of employees; and

(C) Be maintained for not less than 30 years.

(ii) Authorized personnel rosters shall be maintained for not less than 30 years.

(iii) Medical records shall be maintained for the duration of the employment of each employee plus 20 years, or 30 years, whichever is longer.

(3) In the event that the employer ceases to do business and there is no successor to receive and retain his records for the prescribed period, these records shall be transmitted by registered mail to the Director, and each employee individually notified in writing of this transfer.

(4) Employees or their designated representatives shall be provided access to examine and copy records of required monitoring and measuring.

(5) Former employees shall be provided access to examine and copy required monitoring and measuring records reflecting their own exposures.

(6) Upon written request of any employee, a copy of the medical record of that employee shall be furnished to any physician designated by the employee.

(n) *Reports.* (1) Not later than 1 month after the establishment of a regulated area, the following information shall be reported to the OSHA Area Director. Any changes to such information shall be reported within 15 days.

(i) The address and location of each establishment which has one or more regulated areas; and

(ii) The number of employees in each regulated area during normal operations, including maintenance.

(2) Emergencies, and the facts obtainable at that time, shall be reported within 24 hours to the OSHA Area Director. Upon request of the Area Director, the employer shall submit additional information in writing relevant to the nature and extent of employee exposures and measures taken to prevent future emergencies of similar nature.

(3) Within 10 working days following any monitoring and measuring which discloses that any employee has been exposed, without regard to the use of respirators in excess of the permissible exposure limit, each such employee shall be notified in writing of the results of the exposure measurement and the steps being taken to reduce the exposure to within the permissible exposure limit.

(o) *Effective dates.* (1) Until January 1, 1975, the provisions currently set forth in § 1910.93q of this Part shall apply.

(2) Effective January 1, 1975, the provisions set forth in § 1910.93q of this Part shall apply.

APPENDIX A—SUPPLEMENTARY MEDICAL INFORMATION

When required tests under paragraph (k)(1) of this section show abnormalities, the tests should be repeated as soon as practicable, preferably within 3 to 4 weeks. If tests remain abnormal, consideration should be given to withdrawal of the employee from contact with vinyl chloride, while a more comprehensive examination is made.

Additional tests which may be useful:

A. For kidney dysfunction: urine examination for albumin, red blood cells, and exfoliative abnormal cells.

B. Pulmonary system: Forced vital capacity, Forced expiratory volume at 1 second, and chest roentgenogram (posterior-anterior, 14 x 17 inches).

C. Additional serum tests: Lactic acid dehydrogenase, lactic acid dehydrogenase isoenzyme, protein determination, and protein electrophoresis.

D. For a more comprehensive examination on repeated abnormal serum tests: Hepatitis B antigen, and liver scanning.

(Secs. 6 and 8, 84 Stat. 1596, 1599 (29 U.S.C. 655, 657); Secretary of Labor's Order No. 12-71, 36 FR 8754)

Signed at Washington, D.C., this 1st day of October, 1974.

JOHN STENDER,
Assistant Secretary of Labor.

[FR Doc.74-23178 Filed 10-1-74;3:54 pm]

APPENDIX III: SOURCES OF EMISSION AND CONCENTRATIONS IN AMBIENT AIR OF VCM IN THE VC-PVC INDUSTRIES 83/

SUMMARY OF VCM CONCENTRATIONS IN PVC FABRICATION FACILITIES

Type of plant	Concentrations			Fraction > 1 parts per million
	Maximum	Minimum	Mean	
Film and mold (7 plants):				
[illegible] data:				
(a) Breathing zone samples	12	<.3	3	2/5
(b) Area samples	8	<.3	1.2	1/11
(c) Source samples	340	<.3	18	10/22
Pipe and conduit (2 plants):				
Industry data:				
(a) Breathing zone samples	<10	<.1	<1	4/21
(b) Area samples	35	<.1	6	16/20
(c) Source samples	540	<.1	142	10/17

SUMMARY OF VC EXPOSURE LEVELS IN A PVC POLYMERIZATION PLANT

Job	Sampler	TWA	Peak
Solvent area:			
Control room	NIOSH	1	3
	Company	<1	1
Control room	NIOSH	7	7
	Company	2	3
"B" autoclave operator	NIOSH	2	[1] 77
	Company	6	72
Weighmaster	NIOSH	<1	1
	Company	<1	<1
Flash dryer operator	NIOSH	1	4
	Company	1	4
Operations mechanic	NIOSH	1	1
	Company	42	78
Still operator	NIOSH	6	11
	Company	<1	<1
Dispersion area:			
Control room	NIOSH	7	12
	Company	7	12
Utility filter	NIOSH	9	77
	Company	28	803
Weighmaster	NIOSH	3	10
	Company	14	35
Charging operator	NIOSH	10	38
	Company	8	38
Dryer operator	[illegible]	30	83
	[illegible]	34	357
Board operator	[illegible]	7	23
	Company	8	88
Laborer	NIOSH	7	13
	Company	27	283
Modified dispersion area:			
Control room	NIOSH	2	2
	Company	2	4
Reactor maintenance	NIOSH	—	—
	Company	[1] 82	82
Pipefitter-maintenance	NIOSH	—	—
	Company	[1] 23	48
Insulator-maintenance	NIOSH	[1] <1	<1
	Company	[1] 2	2
Utility operator	NIOSH	2	3
	Company	3	115
Autoclave operator	NIOSH	2	4
	Company	4	43

[1] Air-supplied respirator in use.

△ Performing nonroutine maintenance activities.

83/ U.S. Senate. Subcommittee on the Environment. op. cit. p. 51-53.

MAJOR VINYL CHLORIDE EMISSION SOURCES IN POLYVINYL CHLORIDE POLYMERIZATION AND COPOLYMERIZATION PLANTS

SOURCES OF VINYL CHLORIDE EMISSIONS	WORK PRACTICES AND CONTROL PROCEDURES THAT CAN BE UTILIZED TO REDUCE AND/OR ELIMINATE THE EMISSIONS
1. Polymerization reactor cleaning	(a) Reduction in the frequency of cleaning. (b) Automate cleaning process. (c) Maximize purging of reactor before and during employee entry into reactor. (d) Employee use of air supplied respirators (type prescribed by OSHA) when cleaning reactors.
2. Venting vinyl chloride from processing equipment internally within the plant.	Repipe vented vinyl chloride emissions to a recovery system or completely remove vinyl chloride from vented air prior to release.
3. Quality control sampling of process.	(a) Redesign sampling points to eliminate excess pipe downstream of sampling valves in order to reduce the amount of vinyl chloride lost after sampling. (b) Employee collecting sample should wear air supplied respirator as prescribed by OSHA.
4. Process leaks from such things as pumps, valves, flanges, gaskets, etc.	(a) Use direct reading vinyl chloride sampling device on a routine basis for early detection of process leaks. (b) Change pump seals, agitator packing, etc. to designs better suited to prevent leaks.
5. Tank car loading and unloading	(a) Eliminate vinyl chloride that is exhausted while loading and unloading tank cars by piping changes and venting to recovery system or completely removing vinyl chloride from vented air prior to release. (b) Employee use of air supplied respirators (type prescribed by OSHA) while connection and disconnecting lines.
6. Vinyl chloride monomer filter changing.	(a) Reduce frequency of monomer filter changing. (b) Employee use of air supplied respirator (type prescribed by OSHA) while changing or cleaning filter.
7. Polyvinyl chloride waste disposal	Properly cover all polyvinyl chloride waste barrels, drums, bins, etc.
8. Packaging (bagging and drumming of polyvinyl chloride).	(a) Improve local exhaust ventilation at bagging and drumming stations to reduce polyvinyl chloride dust and vinyl chloride gas emissions. (b) Clean baghouses and other control devices frequently to insure top efficiency of ventilation system. (c) Employee use of air supplied respirators type prescribed by OSHA) while cleaning baghouse.

MAJOR VINYL CHLORIDE EMISSION SOURCES IN VINYL CHLORIDE MONOMER PRODUCTION PLANTS

SOURCES OF VINYL CHLORIDE EMISSIONS	WORK PRACTICES AND CONTROL PROCEDURES THAT CAN BE UTILIZED TO REDUCE AND/OR ELIMINATE THE EMISSIONS
1. Tank car loading and unloading	(a) Eliminate vinyl chloride that is exhausted while loading and unloading tank cars by piping changes and venting to recovery system or completely removing vinyl chloride from vented air prior to release. (b) Employee use of air supplied respirator (type prescribed by OSHA) while connecting and disconnecting lines.
2. Quality control sampling of process	(a) Redesign sampling points to eliminate excess pipe downstream of sampling valves in order to reduce the amount of vinyl chloride lost after sampling. (b) Employee collecting sample should wear air supplied respirator as prescribed by OSHA.
3. Process leaks from such things as pumps, valves, flanges, gaskets, etc.	(a) Use direct reading vinyl chloride basis for early detection of process sampling device on a routine em leaks. (b) Change pump seals, etc. to designs better suited to prevent leaks.

APPENDIX IV: CURRENT OCCUPATIONAL EXPOSURE LIMITS FOR VINYL CHLORIDE (VCM) IN NINE COUNTRIES

Current Exposure Limits for VCM in Nine Countries[84]/

Canada(Ontario)	10 ppm TWA, 25 ppm ceiling
England	50 ppm ceiling, 25 ppm TWA
France	no official regulation
Holland	50 ppm ceiling
Italy	50 ppm ceiling
Japan	committee recommendation expected by end of 1974
Norway	temporary ban on PVC production
Sweden	1 ppm TWA adopted on Oct. 14, 1974
West Germany	50 ppm ceiling with proviso that exposures be kept as low as possible

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84/ Clnck, G. The Best Available Evidence. Job Safety and Health, v. 3, no. 1, Jan. Jan. 1975. p. 10.

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